CROSSVENT-4
INTENSIVE CARE/TRANSPORT VENTILATOR

OPERATION & SERVICE MANUAL

CATALOG #4404
revision: 122606

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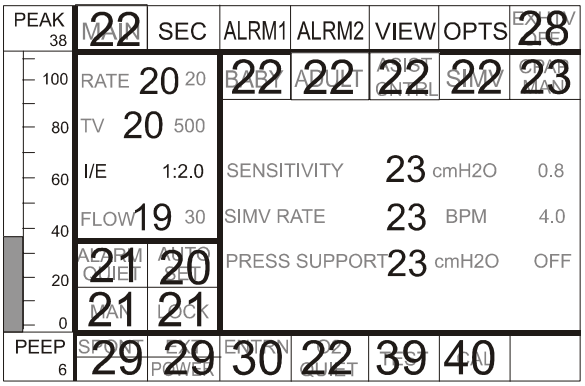
TABLE OF CONTENTS

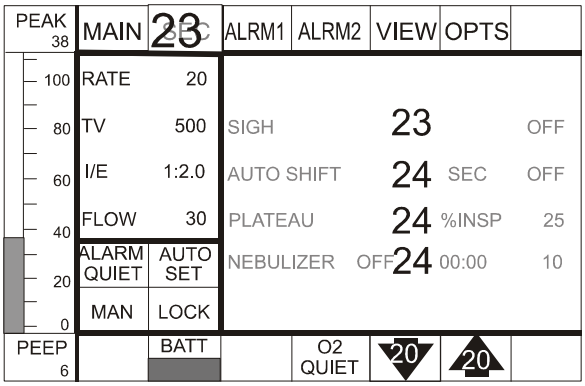
QUICK REFERENCE 1
ADDENDUM 1 2
ADDENDUM 2 2
ADDENDUM 3 3
I. PATIENT SAFETY, WARNINGS, AND CAUTIONS 5
WARNINGS 5
CAUTIONS 9
NOTES 11
SYMBOLS 14
II. GENERAL DESCRIPTION 15
A- INTRODUCTION 15
III. USER INTERFACE, CONNECTIONS AND SPECIFICATIONS 17
A- MANUAL CONTROLS AND MENU DISPLAYS 19
B- INFORMATIONAL DISPLAYS AND INDICATORS 29
C- CONNECTORS & MISC. 31
D- ADDITIONAL SPECIFICATIONS 35
IV. ACCESSORIES AND PATIENT CIRCUIT 36
A- EQUIPMENT AND ACCESSORIES 36
B- INSTALLATION 37
C- PATIENT CIRCUIT CONNECTIONS 38
V. TESTS, CALIBRATION AND TROUBLESHOOTING 39
A- TEST MENU (SELF-DIAGNOSTICS) 39
B- CALIBRATION MENU 40
C- OPERATIONAL TROUBLESHOOTING 42
VI. OPERATING INSTRUCTIONS 45
A- PRELIMINARY STEPS 45
B- DETAILED OPERATING INSTRUCTIONS 46
C- SUMMARY OF OPERATING INSTRUCTIONS 48
VII. CLEANING, STERILIZATION AND PACKING 49
A- CLEANING AND STERILIZATION 49
B- PACKING FOR SHIPMENT 50
VIII. THEORY OF OPERATIONS 52
A- SYSTEM COMPONENTS 55

B- ASSIST CONTROL MODE 56
C- SIMV (Synchronized Intermittent Mandatory Ventilation) MODE 57
D- CPAP (Continuous Positive Airway Pressure) 58
E- AUTO SHIFT AND BACKUP MODALITIES 59
IX. MAINTENANCE AND SERVICE 60
A- VENTILATOR CHECK-OUT PROCEDURES 60
B- RECOMMENDED TOOLS AND TEST EQUIPMENT 70
C- PREVENTATIVE MAINTENANCE 71
D- PNEUMATIC CALIBRATION 74
E- TECHNICAL TROUBLESHOOTING CHART 83
F- DISASSEMBLY & REASSEMBLY INSTRUCTIONS 85
X. PARTS LIST AND SCHEMATIC DIAGRAMS 88
A- REPLACEMENT PARTS LIST 88
B- SCHEMATICS 91
WARRANTY 101
APPENDIX A 102
ABBREVIATIONS 102
APPENDIX B 103
DEFAULT SETTINGS 103
APPENDIX C 104
SUMMARY OF PARAMETER RANGES / ACCURACIES 104
APPENDIX D 105
SUMMARY OF DISABLED FUNCTIONS 105
APPENDIX E 106
FAIL-TO-CYCLE ALARMS 106
APPENDIX F 107
EUROPEAN AGENT 107
INDEX 108

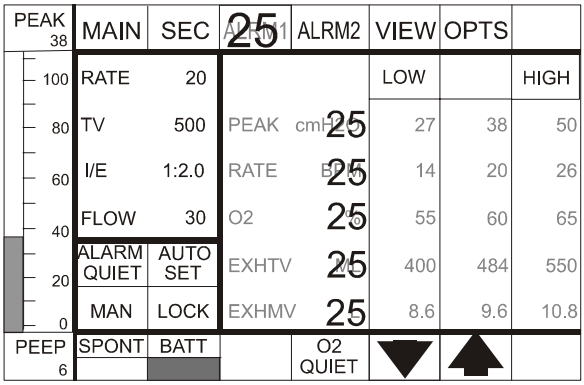
QUICK REFERENCE



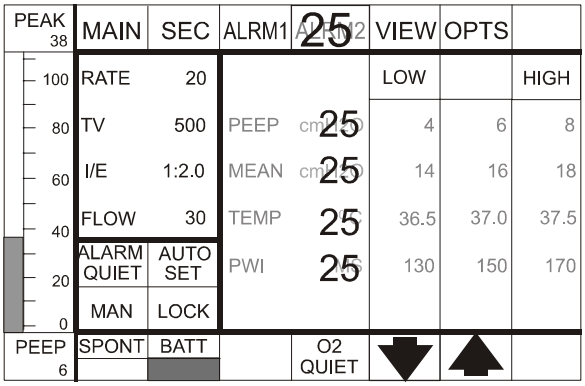
MAIN MENU



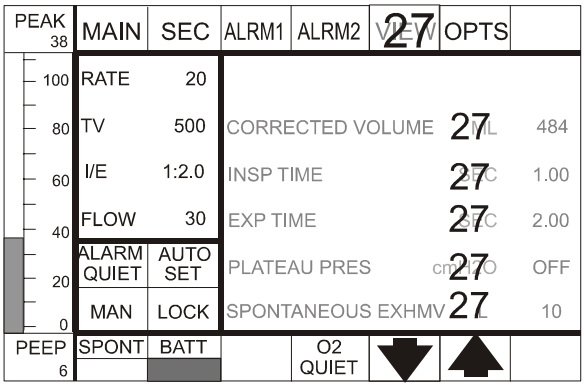
SECONDARY MENU



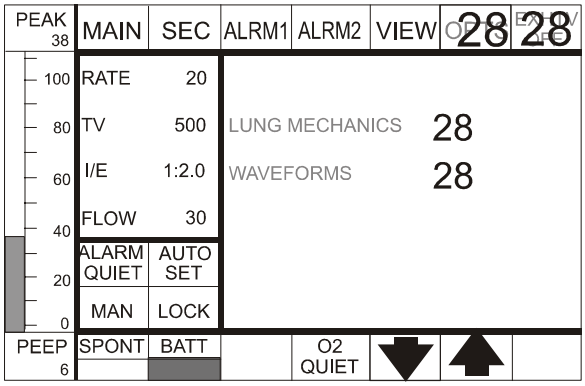
PRIMARY ALARM MENU



SECONDARY ALARM MENU



VIEW MENU



OPTIONS MENU

BACKLIGHT.....21

CONTRAST.....22

ADDENDUM 1

EXHALED TIDAL VOLUME

Exhaled tidal volume and minute volume monitoring is an option with the CV-4 ventilator. If your unit is supplied without these options, please disregard all mention of these functions in this manual.

There are two different pneumotachs for the Crossvent. They are not interchangeable. This manual is written for the pneumotach, catalog #4408. They can be identified by the fittings on the end of the tubes. Catalog #4407 has female fittings to mate with male fittings on the Crossvent. Catalog #4408 has male fittings to mate with female fittings on the Crossvent. When ordering, be sure to order the correct one for your Crossvent.

The pneumotach, catalog #4407, is for use in adult mode only and is accurate for tidal volumes from 200 to 2500 ml and flow rates from 13 to 140 LPM. Its accuracy is ±15%. Exhaled T.V. is disabled in the BABY mode. Once the mode is changed and it is re-enabled, it must be manually turned on.

ADDENDUM 2

AIR ENTRAINMENT

When equipped with the Air Entrainment Module, the CV-4 is able to supply either 100% or 50% (nominal) oxygen during transport, without the use of compressed air. A unique feature of the entrainment system is the ability to deliver repeatable volumes during volume limited ventilation, with relatively constant oxygen concentration.

When the air entrainment control on the right side of the CV-4 is turned to the ON position, a sophisticated, multiple venturi system is activated, which draws in ambient air and dilutes the **100% O2 supply** gas to a nominal 50% concentration.

An additional advantage of using entrainment is that the oxygen supply consumption will be reduced, thereby increasing the operating time on a given supply of gas.

WARNING: Operation of the Crossvent in a contaminated environment can be hazardous when entrainment is used.

NOTE: With entrainment on, flow accuracy from 5 - 100 LPM is ±10% or 1 LPM, whichever is greater, and with a flow of 100 LPM and over, flow accuracy is within 15% of displayed flow. No accuracy is claimed below 5 LPM.

When air entrainment is on, verify the message "ENTRN" is displayed in the entrainment on window to the left of O2 Quiet.

Set the FLOW after entrainment is turned on since the flow calibration is automatically adjusted for entrainment.

It is not recommended that entrainment be turned on or off while ventilating. However, if this should become necessary, then it should be done during the expiratory phase of the breathing cycle.

Compliance calibration should only be performed with entrainment turned off.

ADDENDUM 3

CHARGERS AND INVERTERS

This addendum explains some of the requirements for connecting a Bio-Med Devices Crossvent ventilator to a charger or AC adapter. It is important that the correct charger be used and if a Crossvent is to be used in a vehicle with an AC generating device (inverter), it must comply with certain requirements.

1. LAND OPERATION

When using an AC adaptor to either run the Crossvent or to charge the batteries, only the Jerome Industries model WSZ116M (16VDC 3A) charger supplied by Bio-Med Devices should be used.

The Bio-Med charger has been thoroughly tested for proper operation with the Crossvent to make sure that all standards are met. This includes all of the applicable standards for safety, EMI/RFI, power surges, and leakage. It is approved for medical applications and conforms to FDA, CE, UL, and other required standards.

Although other forms and brands of chargers may operate the Crossvent, there is no guarantee of system reliability or conformance to required standards.

Should an emergency arise and it becomes necessary to operate the Crossvent without the Bio-Med charger, use only a charger that is approved for medical use and complies with all applicable standards. It must produce filtered DC voltage ranging between 12 and 28 volts DC and be rated for continuous 2.5 amps of current.

WARNING: Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.

Should a Crossvent fail to operate or charge from a charger, both the Crossvent and the charger should be returned together to Bio-Med Devices for evaluation.

2. AIR OPERATION – FIXED OR ROTARY WING AIRCRAFT

The aircraft industry is constantly making technical advancements in the areas of composite material construction and weight reduction of installed equipment. Unfortunately, this can conflict with the safe operation of some electronic medical equipment. Composite materials do not work well as a grounding agent for electronic equipment. The weight reduction techniques used in AC inverters often create unsafe conditions when operating electronic medical equipment.

The Crossvent is designed to operate from an external power source delivering 12 to 28 volts DC at a continuous current of 2.5 amps.

WARNING: Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.

It is best to operate the Crossvent from the aircraft's 24-volt DC battery source, rather than an AC inverter. To insure the best "grounding" between the Crossvent and the aircraft metal frame, connect the Crossvent directly to the 24-volt DC power bus through appropriate fusing. This will keep extraneous interference and current leakage to a minimum.

3. **INVERTER OPERATION**

If it is necessary to operate the Crossvent from an AC inverter, similar to KGS Electronics brands, only those inverters in compliance with NEMA standards should be used. Inverters with “split winding” output transformers should not be used with the Crossvent and supplied charger.

The inverter output must be configured like standard household or industrial wiring, where the black wire is “hot”, the white wire is “neutral”, and the green wire is “ground”. The neutral and ground wires should be connected together at one point of the frame so that there is no voltage between them, and there should be 115 volts AC between the hot and neutral wires.

The inverter receptacles must be of the standard three-prong configuration to utilize the hospital-grade cord of the Bio-Med supplied charger. This will keep voltage surges, spurious noise and leakages to a minimum.

Any other type of AC/DC power supply or charger, such as open frame devices, medically approved or not, is not recommended by Bio-Med Devices.

I. PATIENT SAFETY, WARNINGS, AND CAUTIONS

The CROSSVENT-4 ventilator is intended for use only by a qualified practitioner, under the direction of a qualified physician. All personnel operating the ventilator must be completely familiar with the warnings and operating procedures in this manual prior to using the CROSSVENT-4 with patients. As with any life support device, the patients on the CROSSVENT-4 should be visually monitored by competent personnel at all times since life threatening conditions may arise that may not be detected by the alarms. It is essential to test all life-support devices for proper function prior to each use on patients.

A- WARNINGS, CAUTIONS, AND NOTES

The following terms are used throughout this manual:

WARNING - Indicates a procedure or condition that could cause bodily injury.

CAUTION - Signifies a procedure or condition that could damage the equipment.

NOTE - Refers to a procedure or condition that requires special attention.

WARNINGS

- Whenever the CROSSVENT-4 is connected to a patient, a skilled operator should always be present at all times at the ventilator or within hearing range of the ventilator's alarm system.

- If the battery has not been periodically refreshed, the amount of time the Crossvent will operate on battery power may be substantially reduced even though it indicates a full charge.

- High oxygen concentrations may be hazardous to the patient.

- If the gas supply fails or there is a total electrical power failure, the patient may breath atmospheric gas through the failsafe valve. This is, however, only a temporary emergency measure, which requires elevated inspiratory effort and it should be corrected immediately.

- In the aforementioned case, or in the case of entrainment usage, the operation of the Crossvent in a contaminated environment can be hazardous.

- Always operate the CV-4 on battery prior to use to confirm that the battery is functioning.

- In the event of an AC power failure, the CROSSVENT-4 will automatically switch over to battery operation and sound an alarm. The audible alarm may be silenced by pressing the POWER SOURCE window. On a fully charged battery, there will be a minimum of 11 hours of autonomous operation (assuming a 10% on-time of the LCD back light). No further alarm will be sounded until the battery is low. The low battery alarm may then also be permanently silenced by pressing the POWER SOURCE window. It is imperative to restore AC power at this time to assure continued safe operation of the ventilator.

- A patient filter should always be used in the patient breathing circuit to prevent cross contamination

I. PATIENT SAFETY- cont.

- Extreme care should be taken to assure that the patient circuit components are connected correctly. Improper connection can cause malfunction.

- Periodically the CROSSVENT-4 should be operated in the test mode to ascertain that it is functioning properly. A test lung should be ventilated prior to each use to further insure that all modes are functioning correctly. An external spirometer should be used to verify correct volumes and flow rates.

- The patient should never be left unattended after the ALARM QUIET key is depressed since this is followed by a period when the audible alarms are deactivated.

- An audible alarm always indicates an anomalous state which should always be rectified.

- While the temperature, oxygen, and flow sensor alarms may be turned off to permit use of the CROSSVENT-4 without these sensors, it is recommended that they be used at all times. A heated humidifier should never be used without temperature monitoring.

- Always be certain that the Maximum Pressure Limit is set correctly and is operative even when volume limiting, to prevent possible inadvertent administration of high pressure. Increased pressure can be caused by blocked tubes, changes in patient compliance or resistance, or system malfunction.

- If it is desired to temporarily disconnect the patient for clinical interventions such as suctioning, the alarms should be silenced by pressing the ALARM QUIET key. Pressing once will give a 60 second period and pressing twice a 2 min. period, during which the alarms are silenced. If more time is needed the ALARM QUIET key may be pressed again after the alarm sounds. Never turn the power switch off in order to silence the alarms, since this permanently deactivates all alarms.

- Under certain conditions in SIMV with PEEP, when the low peak pressure alarm is set correctly for assisted breaths, there may be no low peak pressure alarm following a patient disconnect until the next assisted breath. This period may be up to 2 minutes. As an added precaution set the low PEEP/CPAP and low exhaled tidal volume alarms so that they are operative.

- Auto Shift/Backup is inoperative in Baby mode.

- When an alarm parameter is turned off, Auto Set is deactivated for that parameter.

- The alarm ports on the front of the CV-4 should never be obstructed.

- For proper operation only the O_2 sensor supplied by Bio-Med Devices may be used.

- Never operate the Crossvent-4 without a battery since it will fail to operate if the plug-in power supply is removed.

I. PATIENT SAFETY- cont.

- The screened ports on the side, back, and bottom of the unit should not be obstructed when the ventilator is in use.

- Only qualified, trained, service technicians should attempt repairs and service when needed. Serious personal injury and/or equipment damage can result if repairs are performed by unqualified personnel.

- The default pressure calibration may not be as accurate as the normal calibration procedure. The normal calibration procedure should be performed instead whenever possible.

- It is imperative to verify that clinically appropriate alarm limits are fully operational following connection of the ventilator to a patient.

- It is important to note that once a sensor has been turned off, the alarms for that sensor are inoperative.

- When using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

- Breathing through the negative pressure relief valve requires a greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse affects to the patient.

- It is extremely important that the Sensitivity control be carefully adjusted to assure proper operation in the CPAP mode.

- Under certain conditions in CPAP, in particular with high flows and low CPAP pressures, if the low peak pressure alarm is set so that no false alarms occur, this alarm may be inoperative if a disconnect occurs. It is therefore extremely important to have the low PEEP/CPAP and low Exhaled Tidal Volume alarms set correctly

- It is important in both Auto Shift and Backup modalities to always set a correct rate, tidal volume and flow to insure proper ventilation in case the patient becomes apneic.

- The default calibration may not be as accurate as the normal calibration procedure. The normal calibration procedure should be performed instead whenever possible.

- To obtain the full 3-minute duration of the fail-to-cycle alarm, the Crossvent must have been powered on for at least 5 minutes.

I. PATIENT SAFETY- cont.

- For proper operation only the temperature sensor supplied by Bio-Med Devices may be used.

- All safety measures must be observed when servicing this device. In particular, the ventilator must be turned off and the power supply disconnected.

- Bio-Med Devices cannot be held responsible for any failure to adhere to the recommendations set forth in this manual.

- Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

- Auto-triggering or missed breaths may occur due to various conditions including, but not limited to, compliance, resistance, rate, flow, PEEP, I:E ratio, and circuit characteristics.

- Do not re-use disposable breathing circuits

- Operation of the Crossvent in a contaminated environment can be hazardous when entrainment is used.

- Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.

I. PATIENT SAFETY- cont.

CAUTIONS

- Clean, dry, medical grade gas sources supplied at 44 to 66 psi (303.6 – 455.4 kPa) unrestricted flow must be used at all times to assure proper operation of the CROSSVENT-4 Ventilator.

- The CROSSVENT-4 should not be steam or gas sterilized as this will result in damage to some of its components.

- When connecting the pneumotachograph (optional) it is important that the proximal and distal tubes be connected to the proper connector to assure correct operation. It is also important that the side ports of the flow sensor head point upward to prevent condensate from collecting in the two pressure tubes. Condensate can cause improper readings and this in turn can cause possible system malfunction. These tubes should be periodically inspected and any condensate should be removed.

- Always connect both flow sensor tubes to the ventilator before attaching sensor head to patient circuit to prevent possible damage to the internal sensing device and also to prevent humidified gas from possibly flowing up the tubes.

- Never block the patient proximal or patient distal connections or flow sensor head with gas supply connected to the ventilator as this can possibly damage the flow transducer.

- Connect the oxygen sensor (optional) upstream of the humidifier since the fuel cell functions better in non-humidified gas.

- Touch screen control keys should be pressed by hand only. Care should be taken not to allow keys to be contacted by sharp objects as damage may result.

- Clean touch screen only with alcohol. Clean the rest of the CROSSVENT-4 unit with mild, non-abrasive, anti-bacterial cleanser.

- Do not place liquids on or near the CROSSVENT-4. Liquid entering the unit can cause severe damage and malfunction.

- When using a nebulizer, the tidal volume should be set as close as possible to the patient's tidal volume in order to minimize waste of medication and minimize the chance of clogging of the pneumotach and exhalation valve.

- It is recommended that the Crossvent-4 never be left with its battery discharged as this will reduce battery life. After discharge of the battery, recharge fully before disconnecting the plug-in power supply. For maximum battery life, periodically discharge the battery fully and then recharge.

- Only replace the battery pack with Bio-Med Devices part #PRT4402. Do not substitute. The cells are non-standard high capacity.

- When using an AC power source, only the power supply provided with the

I. PATIENT SAFETY- cont.

Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation (see Addendum 3 at the beginning of this manual).

- Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications and standards as listed in Section III, Part D.
- Do not use in a MRI room.
- Antistatic or electrically conductive hoses or tubing should not be used.
- When it is necessary to operate the Crossvent from an AC inverter, only inverters in compliance with NEMA standards should be used (see Addendum 3 at the beginning of this manual).

NOTES

- With entrainment on, flow accuracy from 5 - 100 lpm is +/-10% or 1 lpm, whichever is greater, and with a flow of 100 lpm and over, flow accuracy is within 15% of displayed flow. No accuracy is claimed below 5 lpm.

- Battery Backed Memory- When the Crossvent-4 is turned on, it automatically recalls all of the settings stored in memory before it was turned off. This memory is protected by its own separate internal battery which should last for over 7 years (ref. Section IX, Preventative Maintenance). The parameters stored are: all the main functions; high and low alarm limits; secondary modes; oxygen, flow and compliance factor calibrations; and which sensors are on or off. Several factors can cause the battery backed memory to be lost. These are: low battery backed memory battery voltage (service required); defective random access memory (service required); or if the microprocessor is, by chance, storing data in the battery backed memory at the time power is turned off. In this case it is necessary to re-enter the previously set parameters.

- The Maximum Pressure should always be set higher than PEEP in order to achieve the PEEP setting.

- To conserve gas, the Maximum Pressure and PEEP controls should be turned off (fully counter clockwise) when the CV-4 is not in use.

- When an alarm parameter is turned off, auto set is deactivated for that parameter. Whenever an alarm limit is manually entered, it takes precedence over the auto-limit already in memory. When peak pressure is computed in SIMV, if no assisted or controlled breaths are sensed within the 5 breath computation period, another 5 breath period is used. This is repeated until at least 1 assisted or controlled breath is measured.

- Auto Set is inactive in CPAP in the Baby mode.

- The fail-to-cycle alarm may not be silenced using the Alarm Quiet key. The fail-to-cycle alarm may be silenced by pressing the alarm reset button or by pressing a mode key.

- Battery power is substantially reduced if the backlight is on continuously. To conserve battery power, turn the backlight off when it is not needed.

- Sensitivity is disabled in the Baby mode and/or at respiratory rates above 60 bpm.

- Pressure Support is only active during SIMV and CPAP in the Adult mode, but may be set at any time.

- When Baby mode is turned on, Plateau is automatically disabled if it was on and the Plateau display shows "disabled". Once Baby mode is on, Plateau cannot be activated.

- Static Compliance and Airway Resistance are disabled and a "disabled by no plat" message is displayed whenever Plateau is turned off.

I. PATIENT SAFETY- cont.

- To exit an Options menu, press any menu key.

- The wall plug-in power supply is furnished for 117 VAC, 60 Hz or 220 VAC, 50 Hz operation, as required. It is not possible to overcharge the battery. In order to maximize battery life, periodically discharge the battery fully and then recharge. Additionally, always keep the battery fully charged when not in use.

- In the Pressure calibration menu, after pressing the default key, it is important to then perform the zero pressure calibration as outlined in the instructions. Warning: the default calibration may not be as accurate as the normal calibration procedure. The normal calibration procedure should be performed instead whenever possible.

- It is important to use the correct reference gases (100 and 21%) when performing the Oxygen sensor calibration. A worn out sensor will not calibrate accurately.

- During normal operation, the microprocessor automatically zeroes the flow channel pressure transducer during every inspiration, in order to compensate for drift. During this period, a small amount of dry gas (less than 0.1 lpm) is flushed through each of the pneumotach tubes to prevent moisture from condensing.

- Since it is not possible to damage the Crossvent-4 ventilator by normal use of its keys and control knobs, the user is encouraged to experiment with the Crossvent-4 settings while the unit is not connected to a patient.

- Reverse field on the display indicates that a parameter has been selected and may be adjusted using the arrow keys.

- The Auto Set key <u>should always be used to establish initial alarm limits</u>. These may be used for patient monitoring, in order to facilitate setup or may be set temporarily until “custom limits” are entered to suit specific clinical requirements. Any or all of the limits may then be manually changed.

- If it is desired to deactivate the oxygen, temperature or flow sensors, select the desired function, e.g., temp. Scroll the lower limit down to off. The temperature function is now inoperative. The function may be reactivated at any time by pressing temp, and scrolling the low limit up. The temp. sensor is now reactivated. This allows the ventilator to be used without the temperature, oxygen and/or flow sensors. When a sensor is off, it may be disconnected while the ventilator is in use, without causing an alarm.

- For blended gas, the Bio-Med Devices blender should be used.

- It is recommended that an external filter/water trap be used at all times in order to provide greater protection to the internal components of the Crossvent-4.

- For greatest accuracy, verify flow using a 60% O2 gas supply, making certain that the pressure to the CV-4 inlet remains within specified pressure limits (44-66 psi, 303.6 – 455.4 kPa) at all flows.

- If a period longer then 60 sec passes before pushing BATT block when the

I. PATIENT SAFETY- cont.

Crossvent is first turned on, an audible alarm will sound. When BATT block is pushed, the audible alarm will also be silenced.

- Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

- Exhaled minute volume indicates a projected or anticipated minute volume based on the current exhaled tidal volume readings.

- Spontaneous exhaled minute volume is updated with each breath and indicates an actual minute volume of only spontaneous breaths over the past minute.

- It is not recommended that entrainment be turned on or off while ventilating. However, if this should become necessary, then it should be done during the expiratory phase of the breathing cycle.

- 20 minutes of operation after low battery alarm assumes a properly maintained battery in good condition.

- The battery should be replaced at least every two years. Only use batteries supplied by Bio-Med Devices, part #PRT4402.

- When in BABY/CPAP mode, Nebulizer is automatically disabled if it was on and the nebulizer display shows “DISABLED BY BABY CPAP”.

- Because nebulization only takes place during inspiration, less medication is required than if it were during both inspiration and expiration.

- To conserve gas, the Maximum Pressure and PEEP controls should be turned off (fully counter clockwise) when the CV-4 is not in use.

- Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

SYMBOLS

Type BF Equipment

Date of Manufacture

Direct Current (DC)

Connector Polarity

Must be disposed of in accordance with WEEE Directive.
At the unit's "end of life", it may be returned to the manufacturer for proper reclamation.

It is essential that these instructions be read and complied with prior to operating this product.

On

Off

II. GENERAL DESCRIPTION

A- INTRODUCTION

The CROSSVENT-4 Intensive Care/Transport Ventilator is an ultra compact, electronically controlled, time cycled, volume or pressure limited ventilator with intensive care capabilities. It provides a wide range of operating parameters to allow ventilatory

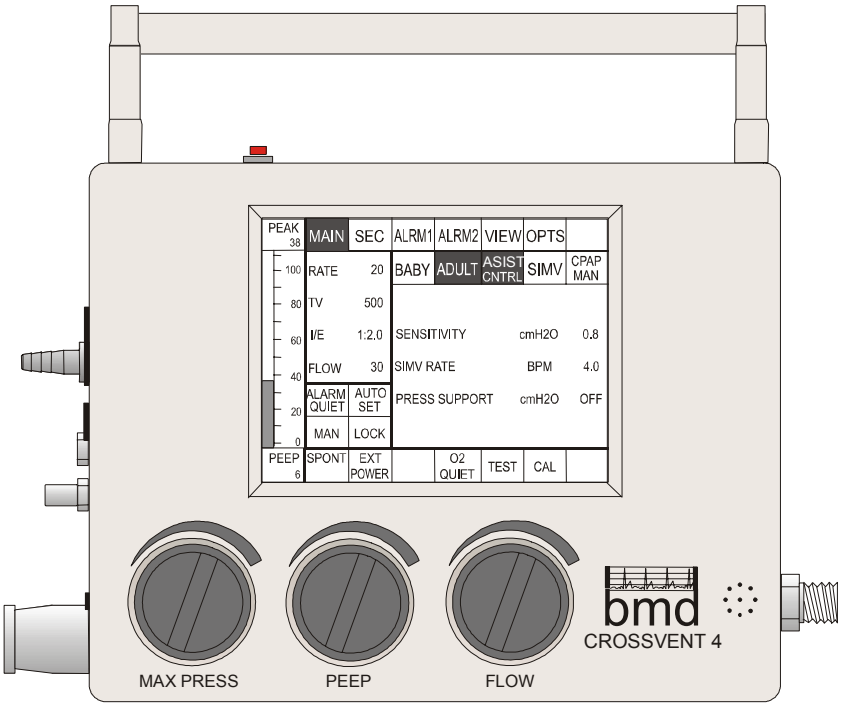


Fig. 1 - CV-4 FRONT PANEL

support of patients from adult to neonate. It may be used either as a pulsatile flow device or with constant flow in the Baby mode. The CROSSVENT-4 delivers the same oxygen concentration as the supply gas.

The ventilator's microprocessor provides all operational functions, as well as monitoring the patient and providing alarms. It allows the user to enter many different operational and alarm parameters to accommodate a wide variety of clinical situations. It also makes possible such advanced functions as automatic setting of alarm limits and the computation of more complex parameters such as Pressure Wave Index™ (PWI™), mean pressure and patient compliance.

Using its auto-set feature, the main alarms of the CROSSVENT-4 may all be set in a matter of seconds with a single keystroke. The CROSSVENT-4's unique, patented, Pressure Wave Index™ allows detection of changes in patient resistance and compliance in difficult to monitor situations such as pressure limited operation.

Airway pressure is sensed using an internal solid-state pressure transducer, and pressure is displayed as a bar graph on the LCD. The patient inspiratory effort is also sensed using a solid-state pressure transducer. An optional flow transducer is available to measure exhaled tidal and minute volume. An absolute pressure transducer monitors atmospheric pressure and automatically compensates for altitude changes.

II. GENERAL DESCRIPTION- cont.

Since the CROSSVENT-4 is totally separable from a compressor and since it may be used with any 55 ±20% psi (379±20% kPa) gas source, it is extremely versatile. It may be used in most areas of the hospital and in transport. It may be mounted on a compressor, on a pedestal stand, a cart, a wall bracket, or a bed rail. It may also be mounted in vehicles such as helicopters and ambulances.

CAUTION: Do not use in a MRI room.

The CROSSVENT-4 has an internal battery which provides power during transport and in the event of an AC power failure. If the external power should fail, the ventilator automatically switches to its internal battery and sounds an alarm. The ventilator will function on a fully charged battery for a minimum of 11 hours. Whenever external power is restored, the CROSSVENT-4 switches back to external power operation. It will charge the battery from its internal charging circuit whenever external power is available.

The CROSSVENT-4 Ventilator's extreme reliability is made possible by:

1- The absence of rotating or sliding mechanical parts.
2- An absolute minimum of moving parts.
3- An extremely low total parts count.

In addition to increased patient safety, the high reliability insures low downtime and thus more economical use.

The CROSSVENT-4 provides a complete array of features and ventilatory modes and functions which include:

Microprocessor control of all operational functions and monitoring.
Displays and alarms for Peak, Mean and Plateau pressures.
Exhaled Tidal Volume and Minute Volume displays & alarms (optional).
Programmability and expandability.
Built-in triggered demand flow for minimum work of breathing during SIMV and CPAP and a simplified system design.
Integral Assist Control, SIMV, CPAP, PEEP, Pressure Support and End Inspiratory Plateau functions.
Selection of automatic mode change or backup breath modalities in SIMV or CPAP.
RS-232 input for PC interface for software updates.
Waveform screen.
Lung Mechanics screen.

III. USER INTERFACE, CONNECTIONS AND SPECIFICATIONS

Careful attention has been paid to the human interface of the CROSSVENT-4. Its Graphic LCD, with touch screen keypad, makes it the most user friendly ventilator for today and tomorrow. Several menus are available on the LCD. These include:

Main functions
Secondary functions
Primary Alarms
Secondary Alarms
Viewable only functions
Lung Mechanics
Waveforms

Each menu is divided into several sections:

Airway Pressure bar graph.
Menu line.
Permanent Function Keys: RATE; TIDAL VOLUME; UP and DOWN Arrows; ALARM QUIET; AUTO SET; MANUAL; LOCK; O_2 QUIET.
Displays and Indicators: Flow; I/E Ratio; insp. source; power source.
Selectable functions area.

A menu is selected simply by pressing any menu key in the menu line.

Procedure for selecting a function and adjusting its setting:

A function is selected by touching the window (key) labeled with the function name. This is best done with the tip of the finger or even the fingernail. When a function is selected, the function will be shown in "reverse video". This means that the normal dark print on light background will switch temporarily to light print on a dark background.
Once a parameter is selected it may be adjusted using the UP and DOWN Arrow keys. The parameter key may be pressed again to turn it off, i.e., deactivate the function. If the parameter or the arrow keys are not pressed for 30 sec., the parameter key will automatically deactivate parameters. The following are exceptions to the procedure for setting functions:

Modes are selected simply by pressing the desired mode key.

Flow is displayed in the Flow window, but may be changed only with the FLOW Control Knob.

I/E ratio is a display window only. I/E is set indirectly by setting Rate, Tidal Volume and Flow.

All parameters shown in the VIEW menu are for display only. They are set indirectly by other parameters.

NOTE: BATTERY BACKED MEMORY. When the CROSSVENT-4 is turned on, it automatically recalls all of the settings stored in memory before it was turned off. This memory is protected by its own separate internal battery which should last for over 7 years (ref. Section IX-Preventative Maintenance). The parameters stored are: all the main

functions; High and Low alarm limits; secondary modes; oxygen, flow and compliance factor calibrations; and which sensors are on or off. Several factors can cause the battery-backed memory to be lost. These are: low Battery Backed Memory battery voltage (service required); defective random access memory (service required); or if the microprocessor is, by chance, storing data in the battery backed memory at the time power is turned off. In this case it is necessary to re-enter the previously set parameters.

A- MANUAL CONTROLS AND MENU DISPLAYS

1- MANUAL CONTROLS

FLOW CONTROL- A pneumatic needle valve which sets the inspiratory flow from 0- 120 lpm (see fig. 1). Its shaft is encoded by connecting it to a precision, multi-turn, potentiometer. The Flow window displays the flow setting. It is accurate from 1 to 120 lpm.

WARNING: When using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

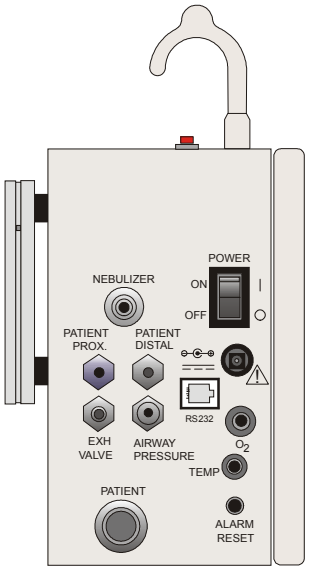


Fig 2. - LEFT SIDE VIEW

MAXIMUM PRESSURE- A pneumatic needle valve which sets the pressure which is applied to the exhalation valve and to the internal diaphragm actuated relief valve (D.A.R.V.) and determines the maximum pressure during assisted and controlled inspirations. It is adjustable from 0 - 120 cmH_2O. It should always be operative and properly adjusted.

NOTE: To conserve gas, the Maximum Pressure and PEEP controls should be turned off (fully counter clockwise) when the CV-4 is not in use.

PEEP (Positive End Expiratory Pressure)- A pneumatic needle valve which sets the PEEP or CPAP (Continuous Positive Airway Pressure) level which is applied to the exhalation valve. It is adjustable from 0- 35 cmH_2O. The PEEP level is determined by observing the system pressure bar graph or with the PEEP/CPAP readout on the secondary alarm menu.

NOTE: The Maximum Pressure should always be set higher than PEEP in order to achieve the PEEP setting.

NOTE: To conserve gas, the Maximum Pressure and PEEP controls should be turned off (fully counter clockwise) when the CV-4 is not in use.

POWER ON/OFF- It is located on the left side of the unit (see fig. 2) and is recessed in order to reduce inadvertent or unauthorized use. It controls the main power to the electronics. If the battery is allowed to fall below 6 volts (well below the Low Battery alarm limit) with the unit operating, the ventilator will turn off independent of this switch. If this occurs, this switch must be turned to Off before the ventilator will operate again, regardless of power source.

WARNING: NEVER USE THE ON/OFF SWITCH TO SILENCE THE ALARMS SINCE THIS RENDERS THE ALARMS PERMANENTLY DISABLED.

ALARM RESET SWITCH (see fig. 2) - Silences the alarm of the **Power Failure/Fail-to-Cycle** circuit, which is a separate section of the main circuit board. It is not under the control of the microprocessor.

WARNING: TO OBTAIN THE FULL 3-MINUTE DURATION OF THE FAIL-TO-CYCLE ALARM, THE CROSSVENT MUST HAVE BEEN POWERED ON FOR AT LEAST 5 MINUTES.

This fail-safe circuit has 3 functions:

1- Monitors the power to the main circuit board. If power is lost, either as a result of turning the main power switch off or a total power failure to the circuit board, i.e., no external power and no battery, it sounds an audible alarm (long tone) and flashes the LED which will continue for 3 min. after failure. This may be less if the unit has been on for less than 5 minutes. The audible alarm is permanently silenced by pressing the Alarm reset switch.

2- Monitors the signals to the A and B solenoid valves. If it does not sense a change in state of the control signal to the appropriate valve, depending on the mode, once every 40 sec. (or every 2 min. for valve B when in the SIMV mode), it sounds an audible alarm (one long, one short tone for Solenoid A; one long, two short tones for Solenoid B) and flashes the LED. When the fail-to-cycle condition is corrected, the alarm is canceled. Additionally, pushing the ALARM RESET switch locks out the audible alarm for 60 sec. Turning the unit off and pressing the switch also permanently silences the alarm.

3- Monitors the microprocessor. If communication between the fail-to-cycle and the microprocessor is lost, it sounds an audible alarm (one long, three short tones) and flashes the LED. The audible alarm may be silenced by pressing the ALARM RESET switch.

2- KEYS COMMON TO ALL MENUS (except OPTS/WAVEFORMS; see fig. 3)

MENU LINE- MAIN (primary functions); SEC (secondary functions); ALRM 1 (primary Alarms); ALRM 2 (secondary alarms); VIEW (viewable-only parameters); OPTS (options); EXHTVOFF (exhaled tidal volume monitoring is off).

RATE- Sets the normal respiration rate. It is adjustable from 5 to 150 bpm in ADULT mode and .6 to 150 bpm in BABY mode. When in SIMV or CPAP, this changes to BAKUP RATE and is used to set the backup rate.

TIDAL VOLUME- Sets the volume of gas delivered during assisted or controlled inspirations. It is adjustable from 5 to 2500 ml. It is accurate from 50 to 2500 ml.

UP and DOWN Arrows- Scroll up and down, at an accelerating rate, any parameter selected and shown in reverse field (with the exception of flow, which may be changed only with the Flow control knob). At the end limits the display remains constant and a tone sounds.

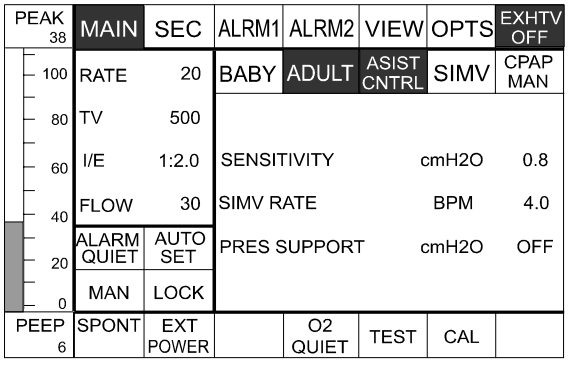


Fig. 3 - MENU AT TURN-ON

AUTO SET (use is optional)- This key must be

depressed 2 times within 5 sec. The key is shown in reverse video and counts from 5 to 1 while average values are computed over 5 breaths and alarm limits are automatically set above and below the average as follows. In Assist Control: High Rate +30%, Low Rate zero; High and Low Peak Press ±30%; High and Low O_2±5% (if sensor is on); High Temp. 40 Deg.C (if sensor is on). Exhaled Tidal Volume, Exhaled Minute Volume, and PEEP are unaffected. All other alarms are set to their extremes or off. In SIMV: same as in Assist Control, with the Low Peak Pressure alarm inactive during spontaneous breaths and the Rate alarm calculated for all types of breaths, including spontaneous breaths. In CPAP: Low CPAP -3 cmH_2O, High CPAP +3 cmH_2O; High Temp. 40 Deg. C (if sensor is on); High and Low O_2 ±5% (if sensor is on).

NOTE: When an alarm is turned off, auto set is deactivated for that alarm. Whenever an alarm limit is manually entered, it takes precedence over the auto-limit already in memory.

When Peak Pressure is computed in SIMV, if no assisted or controlled breaths are sensed within the 5-breath computation period, another 5 breath period is used. This is repeated until at least 1 assisted or controlled breath is measured.

Auto Set is inactive in CPAP in the Baby mode.

ALARM QUIET- Silences the audible alarm for a period of 60 sec. or 120 sec. if pressed twice consecutively. When set, the key is shown in reverse video and counts down from the setting to show its status. If pressed a third time it reactivates the alarm. When the CV-4 is turned on, the Alarm Quiet is activated automatically for 60 sec.

NOTE: The Fail-to-Cycle alarm may not be silenced using this key. The Fail-to-Cycle alarm may be silenced by pressing the ALARM RESET button or by pressing a mode key.

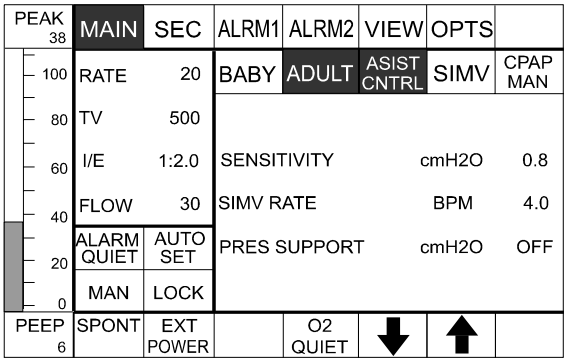


Fig. 4 - MAIN MENU

MANUAL (MAN)- Operative only in the CPAP mode. Provides one normal controlled breath each time it is depressed, with inspiratory time and tidal volume as established by the Rate, Tidal Volume and Flow controls. Minimum expiratory time of 0.2 sec is provided.

LOCK- Locks all other keys, except BACK LIGHT, CONTRAST, ALARM QUIET and MENU keys, until it is pressed again twice within 5 sec. When locked, the key is shown in reverse video.

BACKLIGHT- When the Crossvent is being used on external power, the LCD backlight is on continuously and cannot be turned off. When operating on battery if no key is pressed for a period of 30 sec., the backlight is automatically turned off. If the backlight is desired to be on continuously while in battery mode, then press and hold the pressure bar graph for 3 seconds until it beeps a second time. If the backlight is already on when this is done, it will now be off. Press the bar again to turn it back on. It will remain on until the bar is pressed again or the unit is turned off. Either of these conditions will restore the 30 second timeout.

NOTE: Battery power is substantially reduced if the backlight is on continuously. To conserve battery power, turn the backlight off when it is not needed.

LCD CONTRAST- May be increased by pressing the PEEP key in the lower left corner and decreased by pressing the PEAK key in the upper left corner of the display.

O2 QUIET - Locks out the high O2 audible alarm for 2 minutes so that 100% oxygen may be administered after suctioning. When active, it counts down from 120 sec. It can be reactivated immediately by pressing the key while it is counting down.

3- MAIN MENU (MAIN)

Modes- The ADULT and BABY modes are selected by pressing the corresponding mode key. The selected mode will be shown in reverse field and becomes immediately operative. The modes are:

ADULT mode - Provides pulsatile gas flow, i.e., gas flows only during inspiration. The main parameters set in the Adult mode are: Rate, Tidal volume and Flow rate. Inspiratory Time and Expiratory Time may be read in the View Menu.

BABY mode - Provides a constant flow of gas. In this mode, the TIDAL VOLUME key becomes the INSPIRATORY TIME key, allowing inspiratory time to be set directly and ASIST CNTRL changes to CMV. In addition, the INSPIRATORY TIME window in the View Menu displays TIDAL VOLUME, but it is not accurate and should only be used as a general guide. Although there is no key in the Crossvent dedicated to IMV, intermittent mandatory ventilation may be set using the RATE setting. In the BABY Mode, the following additional limits are established: Maximum flow rate- 29 lpm; Maximum Inspiratory Time- 1.5 sec.; Maximum Tidal Volume- 500 ml. If any of these limits exceeded, the appropriate corresponding window flashes and the audible alarm sounds. The alarm may only be permanently silenced by correcting the setting which is out of range.

WARNINGS: IN THE BABY MODE: AUTOSHIFT/BACKUP, SENSITIVITY, PRESSURE SUPPORT, AND PLATEAU ARE INOPERATIVE, AND EXHALED TIDAL VOLUME AND THE NEBULIZER ARE INOPERATIVE DURING IMV AND CPAP SPONTANEOUS BREATHS. ADDITIONALLY, PEAK PRESSURE AND PEEP READ CONTINUOUS PRESSURE DURING CPAP.

The Assist Control, SIMV and CPAP modes may be selected by pressing the corresponding mode key. The selected mode will be shown in reverse field and becomes immediately operative. The modes are:

ASIST CNTRL (Assist Control) mode - Provides controlled or assist/control ventilation depending upon the Sensitivity setting. If the patient fails to initiate an inspiration, the CROSSVENT-4 will continue to cycle at the respiratory rate set with the RATE control. This key is CMV when in BABY mode.

SIMV (Synchronized Intermittent Mandatory Ventilation) mode - Provides spontaneous and intermittent assisted breaths. The patient is free to initiate spontaneous breaths at a flow rate set with the FLOW control and for the length of time of a normal inspiration as set with the TIDAL VOLUME and FLOW controls. During these spontaneous breaths, a bolus of gas flows to the patient at PEEP or atmospheric pressure. The patient inspires the amount desired and the rest is dumped to atmosphere. At intervals set with the SIMV RATE control, a triggered breath is provided under pressure (synchronized mandatory breath).

CPAP (Continuous Positive Airway Pressure)/Manual mode - Provides spontaneous breaths at PEEP or atmospheric pressure (see spontaneous breaths under SIMV above). The manual key is operative in this mode.

SENSITIVITY- Sets the trigger level below baseline (PEEP or atmospheric) at which an inspiration is initiated. It automatically adjusts for the PEEP level. It is functional in all modes and must be set for use during assisted and spontaneous breaths. It may be set to sense negative pressure changes from 10 cmH_2O to less than 1 cmH_2O below baseline. It should be adjusted for changes in the flow setting.

WARNING: Auto-triggering or missed breaths may occur due to various conditions including, but not limited to, compliance, resistance, rate, flow, PEEP, I:E ratio, and circuit characteristics.

NOTE: Sensitivity is disabled in the BABY mode and/or at respiratory rates above 60 bpm.

SIMV RATE- Determines the rate at which assisted breaths are given in the SIMV mode. Active only in the SIMV mode, but may be set at any time. May be set from 0.6 to 30 bpm.

PRESSURE SUPPORT- May be set from Off to 50 cmH_2O above baseline using the UP and DOWN Arrows. When pressure support is on, it pressurizes spontaneous breaths up to the pressure support setting. When this pressure is achieved, the exhalation valve is allowed to return to baseline pressure, but flow remains on for the duration of a normal assisted breath as set by the RATE and TIDAL VOLUME controls.

NOTE: Pressure Support is only active during SIMV and CPAP in the ADULT mode, but may be set at any time.

TEST- It is only operative immediately after turn-on or from CAL. It is deactivated and replaced by the DOWN ARROW when any key, other than BACK LIGHT, CONTRAST, or ALARM QUIET is pressed after turn-on. Allows the test routine to be run to test ventilator functions (see test procedures in Section V.).

CAL- It is only operative immediately after turn-on or from TEST. It is deactivated and replaced by the UP ARROW when any key, other than BACK LIGHT, CONTRAST, or ALARM QUIET is pressed after turn-on. Allows calibration of the O_2 sensor and calculation of circuit compliance factor (see calibration procedures in Section V.).

4- SECONDARY MENU (SEC)

SIGH- Together with the ARROW keys, turns sigh on and off. When sigh is on, the tidal volume delivered is equal to 1.5 times the normal tidal volume, up to a maximum of 2500 ml in adult mode or 500 ml in BABY mode. In BABY mode, if the inspiratory time and the flow are set so that the tidal volume is above 500 ml, sigh breaths are not delivered.

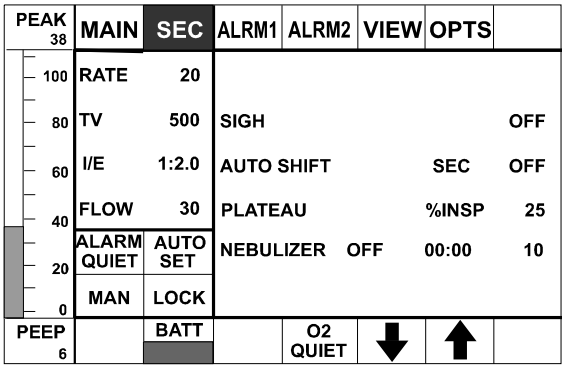


Fig. 5 - SECONDARY MENU

Sigh is operative only in the Assist Control and SIMV modes. When a sigh is delivered, Sigh is indicated in the Inspiratory Source Window. One sigh breath is provided for every 100 normal breaths or one every 7 minutes, whichever occurs first. The CROSSVENT-4 delivers a sigh breath by increasing the inspiratory time of a normal breath. In BABY mode, the inspiratory time is limited to 1.5 seconds. The expiratory time following a sigh is also increased to maintain the same I/E ratio as a normal breath.

AUTO SHIFT (use is optional)- In SIMV or CPAP, sets the delay time waited, to sense an inspiratory effort before shifting into Assist Control mode, sounding an audible alarm and flashing the ASIST CNTRL key. It may be set from 10 to 30 sec. or to Off. When set to Off, the unit is in the backup modality. In the backup modality, if no inspiratory effort is sensed for the period of the Backup Rate (BAKUP RATE) control it will administer backup breaths at the backup rate. Otherwise it is in the Auto Shift modality.

WARNING: AUTO SHIFT/BACKUP IS INOPERATIVE IN BABY MODE.

PLATEAU (End Inspiratory Plateau) (use is optional)- Sets the time interval, following inspiration, from 0.1 to 0.33 of inspiratory time, during which gas flow is shut off, but the exhalation valve is still closed, thus maintaining positive pressure in the alveoli and allowing better gas distribution in the lungs. Plateau is operable for all assisted and controlled breaths. It may be scrolled to off. If the Peak Pressure high alarm limit is reached with plateau activated, both inspiration and plateau are immediately terminated for that breath. The plateau is inoperative during sigh breaths. When BABY mode is turned on, plateau is automatically disabled if it was on and the plateau display shows “DISABLED”. Once BABY mode is on, plateau cannot be activated. Plateau also permits a more accurate measurement of peak intra alveolar pressure and calculation of static compliance. I/E Ratio is calculated with plateau added to the inspiratory time.

NOTE: When BABY mode is turned on, plateau is automatically disabled if it was on and the plateau display shows “DISABLED”. Once BABY mode is on, plateau cannot be activated.

NEBULIZER- The nebulizer provides gas flow at approx. 7 lpm via the nebulizer connector. Nebulization takes place during any patient or machine triggered inspiration, except that it is turned off during plateau and expiration and it is inactive during spontaneous breaths in the BABY mode. When the nebulizer is turned on while in adult mode, the inspiratory time is reduced in order to maintain the same tidal volume. The rate is held constant and therefore the I/E ratio is decreased proportionately. If the nebulizer is turned on while in BABY mode, the inspiratory time is not changed but the TV (displayed in the VIEW menu) is increased appropriately. The nebulizer is automatically turned off whenever the flow rate is below 20 lpm. Set the nebulization period by selecting the nebulizer function and scrolling the time using the arrow keys. Turn on by pressing the OFF/ON key. The time window will count down from the set value to zero and then automatically turn off the nebulizer. The nebulizer may be turned to off at any time by pressing the OFF/ON key, but the time may only be changed when the nebulizer is off.

NOTE and **CAUTION***: The tidal volume should be set as close as possible to the patient’s tidal volume in order to minimize waste of medication and minimize the chance of clogging of the pneumotach and exhalation valve.*

NOTE: Because nebulization only takes place during inspiration, less

medication is required than if it were during both inspiration and expiration.

5-ALARMS

HIGH and LOW Alarm Limits- The high or low limits of an alarm parameter may be selected by pressing the corresponding window for that value. The value is changed using the UP and DOWN Arrows. The low limit may not be scrolled above the high limit and vice versa. When an alarm sounds, the display shifts to the appropriate alarm menu and flashes the alarm parameter which is out of limit. If more than one alarm sounds simultaneously, they each flash. If alarms sound from more than one menu, the menus are prioritized. The CROSSVENT-4 shifts first to the Alarm 1 menu and when these alarms are rectified, it shifts to the Alarm 2 menu and then to the View menu if alarm conditions still exist. Whenever an alarm is active in another menu while the Alarm Quiet is active, the corresponding menu key(s) flashes.

NOTE: Pressing Alarm Quiet allows control of the keyboard while alarms are active.

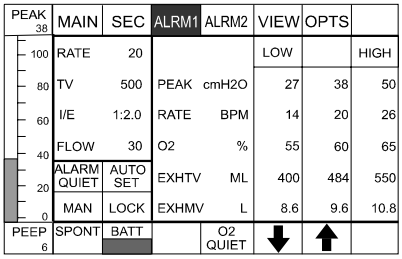


Fig. 6 - PRIMARY ALARM

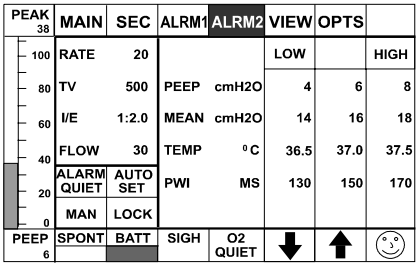


Fig. 7 - SECONDARY ALARM MENU

PARAMETER RANGES AND ALARM LIMITS				
PARAMETER	**DISPLAY RANGE**	**AUTO SET LIMITS**	**MANUAL LIMITS**	
			LOW	**HIGH**
Peak Pressure cmH_2O	0-125	±30%	0-124	1-125
Rate bpm	0-199	Hi +30%	0-159	1-160
O_2	0-100	±5%	0-100	1-105
Exh. Tidal Volume ml	0-4000	None	0-3199	1-3200
Exh. Min. Volume L	0-200	None	0-99	1-100
PEEP/CPAP cmH_2O	0-99	Lo -3 cmH_2O CPAP	-20 to 99	0-100
Mean Pressure cmH_2O	0-125	None	0-124	1-125
Temperature Deg. C	0-45 Hi	+40; Lo - None	0-39	15-40
Temperature Deg. F	32-113	Hi +104;Lo - None	32-103	59-104
PWI ms	0-2000	None	0-1999	1-2000
Plateau Pressure	0-125	None	None	None

VIEW MENU ALARMS- Inspiratory Time and Expiratory Time in Adult Mode; Tidal Volume and Expiratory Time in BABY Mode.

PRIMARY ALARM MENU (ALRM1) monitored parameters and alarms- Standard Alarms are Peak Pressure and Rate. Alarms that can be turned off are O_2, Exhaled Tidal Volume and Exhaled Minute Volume.

SECONDARY ALARM MENU (ALRM2) monitored parameters and alarms- PEEP and CPAP, Mean Pressure, PWI, and Temperature. The last three may be turned off.

ADDITIONAL ALARMS OUTSIDE OF THE ALARM MENUS		
MODALITY	**CONDITION**	**INDICATED BY FLASHING**
ADULT	INSPIRATORY <0.1 SEC.	INSPIRATORY- VIEW MENU
ADULT	INSPIRATORY >3.0 SEC.	INSPIRATORY- VIEW MENU
ADULT or BABY	EXPIRATORY <0.2 SEC.	EXPIRATORY- VIEW MENU
ADULT or BABY	I/E >3:1	I/E KEY
BABY	T_I + FLOW = TV >500 ml	TIDAL VOLUME-VIEW MENU
BABY	FLOW ≥30 lpm	FLOW KEY
ADULT	AUTO SHIFT TIME-OUT	ASSIST CONTROL
ALL MODES	NO EXTERNAL POWER	BATTERY KEY
ALL MODES	LOW BATTERY	BATTERY KEY

NOTES REGARDING ALARMS:

RATE- The monitored rate is calculated and displayed as a rolling average over 10 breaths. In BABY/CPAP mode, the rate is determined by monitoring changes in airway pressure. Under some conditions, this change in pressure may be too small to detect. In this case, adjusting the flow down to a lower flow rate may help. Be sure it is not lowered to a level inappropriate to properly ventilate the patient.

HIGH PEAK PRESSURE- Inspiratory is terminated if the peak pressure reaches the high limit as set except for sigh breaths. During sigh breaths the high peak pressure limit is increased by 1.5 times the display setting (up to 125 cmH_2O).

EXHALED TIDAL VOLUME- (See Addendum 1 at the beginning of this manual.) This reading updates with each breath. During sigh breaths, the high limit is increased by 1.5 times the display setting (up to 2500 ml.) When exhaled tidal volume is set to off, this status is displayed in the upper right corner of all screens, excluding TEST and CAL.

EXHALED MINUTE VOLUME- It is disabled whenever the Exhaled Tidal Volume is turned off.

NOTE: EXHMV indicates a projected or anticipated minute volume based on the current exhaled tidal volume readings.

PEEP and PEAK- displays continuous pressure in the BABY mode in

CPAP.

PEEP/CPAP- displays CPAP when in CPAP mode and PEEP in other modes.
MEAN PRESSURE- is the average pressure of a single breath.

TEMPERATURE- Pressing the Degrees C/Degrees F window and then an ARROW key, toggles between degrees C and degrees F.

WARNING: For proper operation only the temperature sensor supplied by Bio-Med Devices may be used.

PWI- (Pressure Wave Index)™: PWI is the up-slope of the inspiratory portion of the pressure curve. It is defined as the time (in milliseconds) that it takes to go from 5 to 10 cmH_2O above baseline. A change in PWI indicates a change in resistance or compliance and it may be used to detect such changes even when pressure limiting.

DEACTIVATING ALARMS- The alarms for Mean, PWI, Exhaled Tidal Volume, Exhaled Minute Volume, O_2 and Temperature may be turned off by scrolling the low limit down past zero to Off.

WARNING: WHEN AN ALARM PARAMETER IS TURNED OFF, AUTO SET IS DEACTIVATED FOR THAT PARAMETER.

6-VIEW MENU (VIEW - for parameters which may be viewed only)

CORRECTED VOLUME (use is optional)- Displays the volume delivered to the patient in ml. It is computed by subtracting the volume lost in the patient circuit from the set tidal volume. The patient circuit compliance factor must be properly entered in the calibration mode in order to allow an accurate calculation of corrected volume.

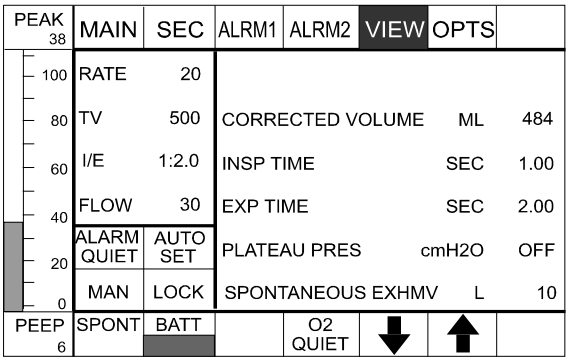


Fig. 8 - VIEW MENU

INSP. TIME- Adult Mode- Displays the inspiratory time established with the TIDAL VOLUME and FLOW controls. The total inspiratory time also includes the end inspiratory plateau if it is turned on. It flashes and alarms whenever the inspiratory time is greater than 3.0 sec. or less than 0.1 sec.

TIDAL VOLUME- BABY Mode- Displays the calculated tidal volume as set with the INSPIRATORY TIME and FLOW controls. This display is not accurate and is intended to be used only as a guide. It flashes and alarms whenever the tidal volume is greater than 500 ml.

EXP. TIME- Displays the expiratory time. Flashes and alarms whenever the expiratory time is less than 0.2 sec.

PLATEAU PRESSURE- Displays the pressure during the end inspiratory plateau.

SPONTANEOUS EXHMV- Displays exhaled minute volume of spontaneous breaths

only. This function is always OFF in BABY mode.

NOTE: Spontaneous exhaled minute volume is updated with each breath and indicates an actual minute volume of spontaneous breaths only over the past minute.

7- OPTIONS MENU (OPTS)

The Options Menu contains optional functions. This menu will display an "OPTION NOT INSTALLED" message for any function which is not installed in the CV-4.

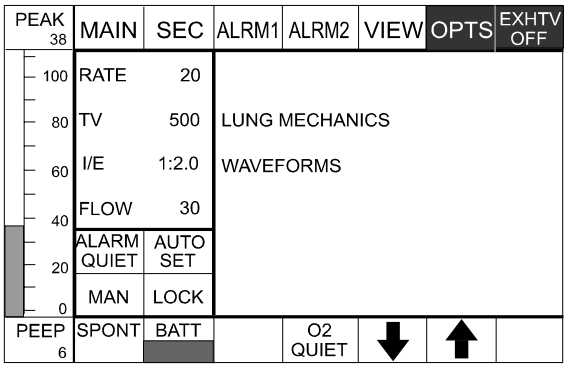


Fig. 9 - OPTIONS MENU

LUNG MECHANICS- Displays the following calculated values:

STAT COMP (Static Compliance)- in ml/cmH_2O.

DYN COMP (Dynamic Compliance)- in ml/cmH_20.

RESIST (Airway Resistance)- in cmH_20/L/sec.

NOTE: Static Compliance and Airway Resistance are disabled and a "DISABLED BY NO PLAT" message is displayed whenever Plateau is turned off.

WAVEFORMS- Displays the pressure waveform as a function of time. The vertical and horizontal scales may be adjusted by pressing the VSCAL (vertical scale) and HSCAL (horizontal scale) keys and then using the UP and DOWN Arrow keys. The full vertical scale may be set to 12, 25, 50, 75, or 100 cmH_2O and the full horizontal scale may be set to 0.7, 1.4, 2.8, 4.2, 5.6, 7.0 or 8.4 sec.

NOTE: To exit an options menu, press any menu key.

8- EXHALED TIDAL VOLUME OFF (EXHTV OFF)

This is displayed when exhaled tidal volume monitoring in the Alarm 1 menu is turned off. Pressing it brings up the Alarm 1 menu with exhaled tidal volume in reverse video. Press the up arrow to turn it on. When on, this block is blank.

B- INFORMATIONAL DISPLAYS AND INDICATORS

1- DOT MATRIX GRAPHICS LCD.

Backlighting enhances the display, but it may be turned off to reduce battery power consumption. It is divided into sections which include the following displays and indicators:

AIRWAY PRESSURE BAR GRAPH-Provides an analog readout in proximal airway pressure from 0 to +110 cmH_2O. It has no moving parts. Above and below the bar graph are numerical values for PEAK and PEEP/CPAP pressures respectively.

FLOW WINDOW- Displays the inspiratory flow set with the Flow knob control.

WARNING: When using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

I/E RATIO WINDOW- Displays the ratio of inspiratory time to expiratory time. This display flashes and an audible alarm sounds whenever: the I/E ratio is greater than 3 to 1, whenever the inspiratory time is greater than 3 sec. or less than 0.1 sec. or whenever the expiratory time is less than 0.2 sec. The alarm may be silenced temporarily by pressing ALARM QUIET. It may be permanently silenced only by rectifying the timing limit violation.

INSPIRATORY SOURCE WINDOW:

SPONTANEOUS- Displays SPONT whenever an inspiration is initiated by the patient's spontaneous effort during SIMV or CPAP, delivered at PEEP or atmospheric pressure or pressurized when pressure support is on.

ASSISTED- Displays ASIST whenever an inspiration is initiated by the patient's spontaneous efforts and delivered under pressure (volume or pressure limited breath), during Assist Control and SIMV breaths.

CONTROLLED- Displays CONTRL whenever an inspiration is initiated by the CROSSVENT-4 timer (volume or pressure limited breath), during Assist Control, SIMV backup and CPAP backup breaths.

SIGH- Displays SIGH during a sigh breath when SIGH is on in the Secondary Menu.

POWER SOURCE WINDOW:

EXTERNAL POWER- Displays "EXT POWER" whenever external power is connected to the CROSSVENT-4.

BATTERY OPERATION- Flashes "BATT" whenever external power is lost and the CV-4 is operating on battery. A simultaneous audible alarm sounds which **may be**

silenced only by pressing the Power Source window. The Power Source window also displays a bar graph which decreases in 20% increments. Restoration of external power will automatically switch the unit to external power operation and begin charging of the battery until full charge is reached.

WARNING: If the battery has not been periodically refreshed, the amount of time the Crossvent will operate on battery power may be substantially reduced even though it indicates a full charge (see Section III, Part C-3).

WARNING: Always operate the CV-4 on battery prior to use to confirm that the battery is functioning.

WARNING: Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.CAUTION: It is recommended that the CROSSVENT-4 never be left with its battery discharged as this will reduce battery life. After discharge of the battery, recharge fully before disconnecting the plug-in power supply. For maximum battery life, periodically discharge the battery fully and then recharge.

Low Battery- Flashes "BATT LOW" and sounds the audible alarm while at least 20 min. of autonomous operation remains. The audible alarm may be permanently silenced by pressing the Power Source window. The ventilator should be switched to external power or removed from service and recharged when this alarm occurs. If the battery is allowed to expend energy to a point below 6 volts (well below the Low Battery alarm limit), the ventilator will shut down independent of the On/Off switch. If this occurs, the external power supply must be used to recharge the battery and the On/Off switch must be turned to Off and then back to On before the unit will operate.

Note: 20 minutes assumes a properly maintained battery in good condition.

ENTRAINMENT ON WINDOW- Indicates "ENTRN" when entrainment is on.

2 - AUDIBLE TONE GENERATOR

Located next to the BMD logo on the front of the unit (Fig. 1), it emits the audible tones to indicate an alarm condition or keyboard actuation. The tone for a standard alarm is rated at 90 dB.

WARNING: It should never be obstructed.

3 - ALARM LED

It flashes during any alarm providing 360-degree visibility. When unit is turned off or loses power, it lights intermittently for 3 minutes. This time may be less if the Crossvent was not powered on for at least 5 minutes prior to loss of power.

C- CONNECTORS & MISC.

Caution: Antistatic or electrically conductive hoses or tubing should not be used.

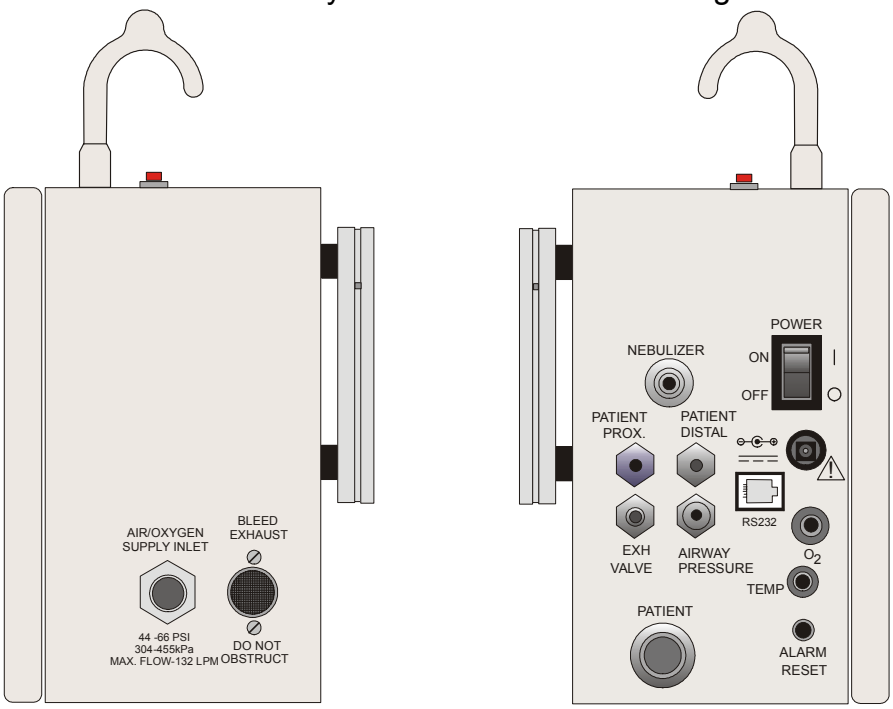


Fig. 10 - SIDE VIEWS

1.Right side

GAS SUPPLY INLET- Male DISS 9/16-18 fitting. Clean, dry, medical grade gas, delivered at 44 to 66 psi (303.6 – 455.4 kPa) pressure at 132 lpm is required.). If an air/oxygen blender is used, then 45 – 75 PSI (310-517 kPa) should be supplied to the blender.

2. Left side

EXTERNAL ELECTRICAL SUPPLY CONNECTOR- This receptacle accepts the plug from the factory supplied, U.L. approved, wall plug-in, power supply module which by necessity meets all the specifications and standards listed in Section III, Part D. Use only Jerome Industries model WSZ116M (16VDC, 3A). The Crossvent should not be used with any other wall plug-in or desktop AC adapter. This is used to operate the ventilator and to charge the battery whenever it is below full charge. The wall plug-in power supply is furnished for 117 VAC, 60 Hz or 220 VAC, 50 Hz operation, as required. It is not possible to overcharge the battery. In order to maximize battery life, periodically discharge the battery fully and then recharge (see Section III, Part C-3). Additionally, always keep the battery fully charged when not in use.

WARNING: Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.

CAUTION: When using an AC power source, only the power supply provided with the Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation.

CAUTION: Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of

the specifications and standards as listed in Section III, Part D.
CAUTION: When it is necessary to operate the Crossvent from an AC inverter, only inverters in compliance with NEMA standards should be used (see Addendum 3 at the beginning of this manual).

PATIENT GAS CONNECTOR- The main patient corrugated hose is attached here. It provides the un-humidified breathing gas mixture to the patient circuit.

EXHALATION VALVE CONNECTOR- Provides the pressure signal to operate the exhalation valve. During inspiration it applies a high pressure signal to the exhalation valve diaphragm which sets the Maximum Pressure Limit. During expiration it provides a zero or PEEP level to the exhalation valve diaphragm.

AIRWAY PRESSURE CONNECTOR- Provides connection of the proximal airway pressure tube to the internal pressure transducer. This allows the CROSSVENT-4 to monitor airway pressure and also to detect patient inspiratory efforts.

PROXIMAL AND DISTAL PNEUMOTACH CONNECTORS- These two connectors provide the pressure signals to the internal transducer that permits the measurement of flow (optional). The proximal connector should be connected to the tube on the pneumotachograph (PNEUMOTACH) which is proximal to the patient. The distal connector is connected to the tube which is more distant from the patient. The pneumotach is attached via its two tubes to these connectors. Flow is measured as the differential pressure across the orifice of the pneumotach.

CAUTION: The pressure connection tubes of the pneumotach should always be mounted vertically to prevent collection of condensate in the pressure tubes. The tubes should be inspected periodically and condensate should be removed. This condensate may cause erroneous readings and thus improper operation of the CROSSVENT-4. Never block these connections with the unit operating as this can damage the internal transducer. Always securely connect both pneumotach lines (proximal and distal) to their respective connectors before inserting the pneumotach in the flow stream. This will prevent possible damage to the internal transducer and will also prevent humidified gas from inadvertently blowing up the pneumotach sensing lines.

OXYGEN SENSOR CONNECTOR (use is optional)- Permits attachment of the O_2 fuel cell sensor. This provides measurement of the oxygen concentration of the patient breathing gas mixture.

WARNING: For proper operation only the O_2 sensor supplied by Bio-Med Devices may be used.

TEMPERATURE SENSOR CONNECTOR (use is optional)- Allows connection of the thermistor temperature probe which provides measurement of the temperature of the breathing gas mixture in the proximal airway.

WARNING: Never use a heated humidifier without monitoring the proximal airway temperature. Excessive temperature can result in severe injury to the patient.

WARNING: For proper operation only the temperature sensor supplied by Bio-Med Devices may be used.

RS-232 COMPUTER INTERFACE (use is optional)- A 6 pin, modular jack is

provided as a convenient PC interface for software updates.

3. Rear of Unit

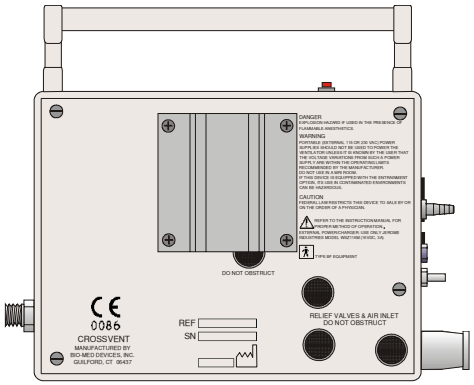


FIG. 11 - REAR VIEW

BATTERY- The battery is located internally. In order to maximize battery life, periodically refresh the battery as described here. Additionally, always keep the battery fully charged when not in use.

To properly maintain and refresh the battery, it is important to periodically fully discharge and then fully recharge it. To do this, first unplug the external power supply from the side of the Crossvent if it is plugged in. Turn the Crossvent on and press the TEST key in the bottom row of the display. Press VALVES and press ON for each valve. (Putting it in test mode will prevent any alarms from sounding and hasten the process by having the backlight and valves on). Leave it this way until the display is blank. This indicates the battery is exhausted. This may take several hours depending on the state of the battery when you begin.

CAUTION: Turn off the unit for at least one minute prior to plugging in the external power supply after a full discharge.

Plug the external power supply back into the side of the unit and into a wall outlet and charge the battery for a minimum of 4 hours. When done, verify battery power by unplugging the external power cord from the side of the unit while it is turned on. The Crossvent should alarm and the power source key in the bottom row should be flashing. Press this key to silence the alarm. The battery bar indicating the remaining battery power should span the entire battery key.

WARNING: If the battery has not been periodically refreshed, the amount of time the Crossvent will operate on battery power may be substantially reduced even though it indicates a full charge.

WARNING: Never operate the CROSSVENT-4 without a battery since it will fail to operate if the plug-in power supply is removed.

WARNING: Although the Crossvent will operate with an external power source from 12 – 28 VDC, when at 12 volts the battery will not charge.

CAUTION: The battery should be replaced at least every two years. Only use batteries supplied by Bio-Med Devices, part #PRT4402.

MAXIMUM PRESSURE RELIEF VALVE- A preset, relief valve exits the rear of the unit. This valve establishes the maximum safety pressure deliverable. It is set at 120 cmH_2O.

WARNING: It should never be obstructed.

NEGATIVE PRESSURE RELIEF VALVE- A preset, negative pressure valve also exits the rear of the unit. It allows the patient to breath ambient air if the entire system should become inoperative. It opens at approximately -4 cmH_2O.

WARNING: It should never be obstructed.

WARNING: Should the use of the negative pressure relief valve become necessary, the operation of the Crossvent in a contaminated environment can be hazardous.

CE MARK- The CE mark displayed on this product signifies that this device is in

compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.

EU Classification: Internally-powered equipment
Continuous operation
BF type applied part
Not suitable for AP or APG

D- ADDITIONAL SPECIFICATIONS

Maximum Safety Pressure:	120 cmH_2O
Pneumatic Power Source:	55 psi ±20% (379 ±20%kPa)[1]
Audible Alarm Characteristics:	90 dB at 10cm (25°C)

Electrical Power Source:
See Addendum 3 at the beginning of the manual

Output:	16.0 VDC, 3 A
Output Protection:	Short Circuit and Overload
Isolation:	Meets IEC601.1, classification BF, UL 544 Patient Care, CSA 125 Risk Class 2G
Maximum Ripple:	<100 mVp-p
Safety:	Approved to UL 544/2601.1, CLU (CSA) 22.1 #125/601.1, TUV EN60601.1 & CE LVD
EMC:	Designed to Level B Requirements of FCC part 15, CISPR11 (EN55011). Less than 1 Volt Output Deviation for IEC801-2, 3, 4, 5, Immunity Tests.

Overall Dimensions

Height:	9" (229 mm)
Width:	11" (280 mm)
Depth:	5" (140 mm)
Weight:	9.5 lbs. (4.32 kg) with standard battery
Operating Temperature:	32 to 104 degrees F. (0 to 40 degrees C)[2]
Storage Temperature:	32 to 122 degrees F. (0 to 50 degrees C)[2]

1. If an air/oxygen blender is used, then 45 – 75 PSI (310 – 517 kPa) should be supplied to the blender.
2. When using the oxygen sensor, then 41 – 104 degrees F (5 – 40 degrees C); battery will not fast charge below 41 degrees F (5 degrees C) nor above 104 degrees F (40 C).

IV. ACCESSORIES AND PATIENT CIRCUIT

A- EQUIPMENT AND ACCESSORIES

1. Unpacking

Examine the shipping carton for signs of damage. Examine the CROSSVENT-4 carton to ascertain whether it has sustained any damage during shipment. Inspect the contents of the shipping carton.

The following is a list of the equipment supplied with the CROSSVENT-4 Intensive Care/Transport Ventilator.

Quantity	Cat. No.	Description
1	4400	CROSSVENT-4 Ventilator
1	2002K[1]	High Flow Blender
1	2013	Pole Mounting Bracket
1	1010	High Pressure Supply Hose - Oxygen
1	1011[2]	High Pressure Supply Hose - Air
1	80011	Disposable Adult Breathing Circuit
1	1020	Test Lung
1	20011	Disposable Infant Breathing Circuit
1	1022	Infant/Pediatric Test Lung
1	4408[3]	Disposable Pneumotach
1	4401	Disposable Patient Filter
1	10003[4]	Temperature Sensor
1	4433	Oxygen Sensor Cell
1	4418	Oxygen Sensor Cell Tee
1	4414[1]	Oxygen Filter/Water Trap
1	4415[4]	Air Filter/Water Trap
1	4404	Instruction Manual
1	--------	Warranty Card
1	4416A	Charger w/Cord, U.S. AC Adapter
1	4416B	Charger w/Cord, Int'l AC Adapter

NOTE: 1- OPTIONAL
2- STANDARD WITH BLENDER
3- SEE ADDENDUM 1 AT THE BEGINNING OF THIS MANUAL; SUPPLIED WITH UNITS WITH EXHALED TIDAL VOLUME MONITORING CAPABILITES ONLY
4- STANDARD WITH INTERNATIONAL ORDERS

B- INSTALLATION

1. MOUNTING

The CROSSVENT-4 Ventilator may be mounted in several different ways depending on the clinical application and surroundings. It may be placed on a tabletop or mounted on a compressor, or a pedestal stand, using its pole mount bracket. This bracket will also accommodate the pole of a wall mount adapter to permit the CROSSVENT-4 to be mounted off the floor.

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to CE. These limits are designed to provide reasonable protection against harmful interferences in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna, increase the separation between the equipment and the receiver, connect the equipment into an outlet on a circuit different from that to which the receiver is connected, or consult the dealer or an experienced radio/TV technician for help.

2. POWER CONNECTIONS

Insert the BMD plug-in power supply output connector into the mating connector on the left side of the ventilator. Plug the power supply into an A.C. outlet. Attach a 50 psi source to the inlet on the right side. The use of an external filter/water trap is highly recommended. The air source may be a compressor or wall or tank compressed air source. All gas supplies should be clean, dry medical grade gas supplied unrestricted at 55 psi ±20% (379 ±20%kPa).). If an air/oxygen blender is used, then 45 – 75 PSI (310-517 kPa) should be supplied to the blender.

CAUTION: When using an AC power source, only the power supply provided with the Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation.

CAUTION: Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications and standards as listed in Section III, Part D.

C- PATIENT CIRCUIT CONNECTIONS

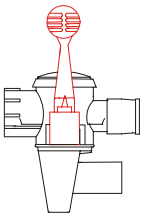
WARNING: A patient filter should always be used in the patient breathing circuit to prevent cross contamination

WARNING: Do not re-use disposable breathing circuits.

NOTES

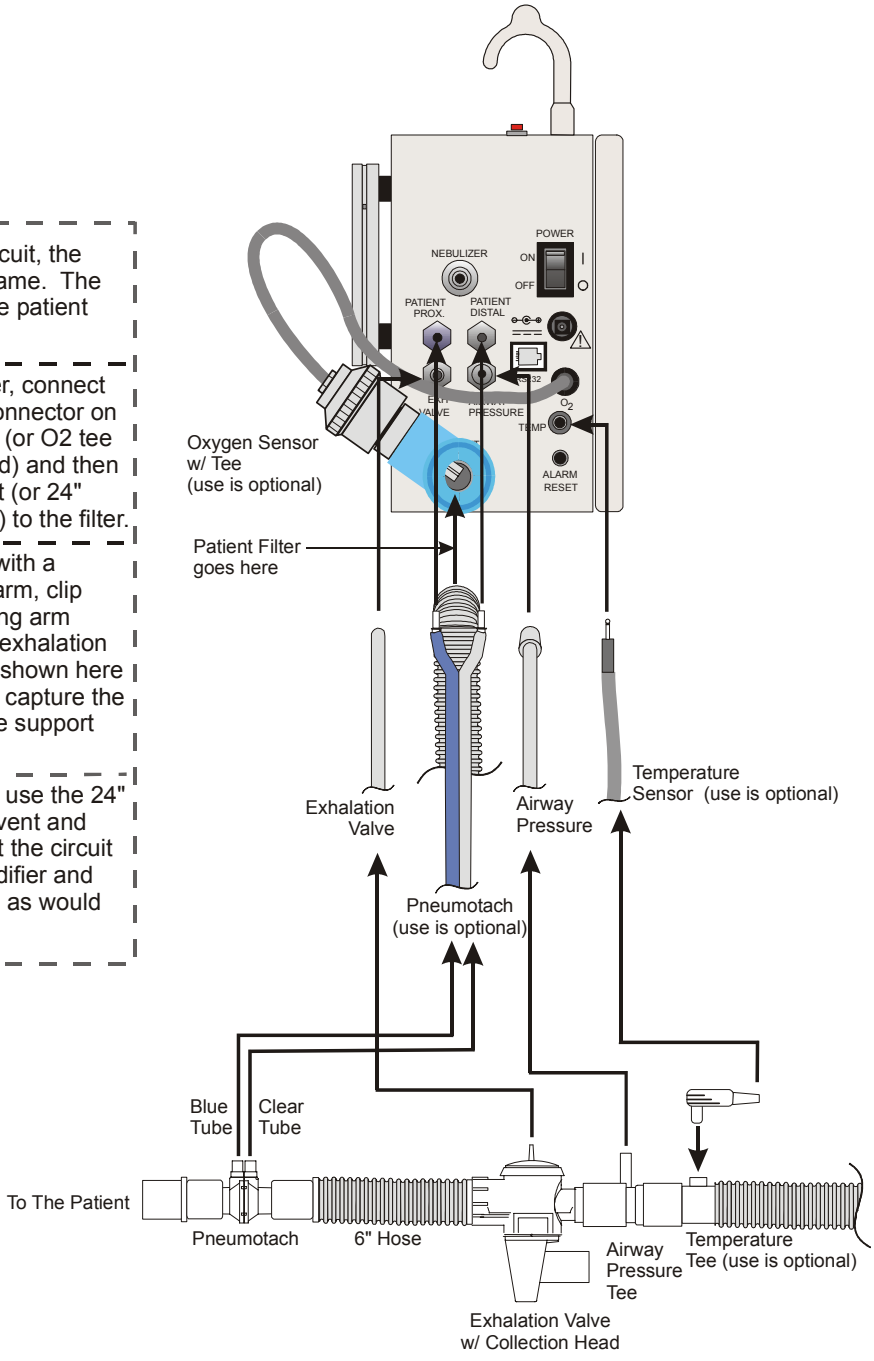
When using the infant circuit, the setup is essentially the same. The pneumotach goes into the patient wye at the patient end.

When using a patient filter, connect it directly to the patient connector on the side of the Crossvent (or O2 tee if the sensor is being used) and then connect the patient circuit (or 24" hose if using a humidifier) to the filter.



For use with a support arm, clip the holding arm onto the exhalation valve as shown here and then capture the ball in the support arm.

When using a humidifier, use the 24" hose between the Crossvent and humidifier. Then connect the circuit to the output of the humidifier and make all the connections as would normally be made.



Adult circuit, catalog #80011, shown

FIG. 12 - CIRCUIT SETUP

V. TESTS, CALIBRATION AND TROUBLESHOOTING

WARNING
ONLY QUALIFIED, TRAINED, SERVICE TECHNICIANS SHOULD ATTEMPT REPAIRS AND SERVICE WHEN NEEDED. SERIOUS PERSONAL INJURY AND/OR EQUIPMENT DAMAGE CAN RESULT IF REPAIRS ARE PERFORMED BY UNQUALIFIED PERSONNEL.

A- TEST MENU (SELF-DIAGNOSTICS)

This menu is primarily for use by someone skilled in the service and repair of the CROSSVENT-4 Ventilator. Items in this menu that are not listed here are functions designed for maintenance personnel and may be found in the service section of this manual under Performance Checks.

To activate the test mode, turn the ON/OFF switch to ON and press the TEST key on the main menu. This key is only enabled immediately after turn on and is disabled as soon as any other key, except ALARM QUIET, BACKLIGHT or CONTRAST, is pressed. The test menu will appear on the LCD and the alarm LED will turn on and turns off when any other key is pressed. It is possible to terminate the test mode and go to the CAL menu by pressing the CAL MENU key or return to normal operation at any time by pressing the MAIN MENU key.

1- LEAKAGE

Connect the patient circuit with a test lung to the Crossvent. Set the Max Pressure to its maximum setting. Set the PEEP to its maximum setting. Set the flow control to 10 LPM. Press enter. The Crossvent will pressurize the system and indicate “TESTING”, followed by either “PASSED” or “FAILED” depending on the results. If it fails the test, check the patient circuit and all connections, and retest.

2- ELAPSED HOURS

Indicates the total accumulated hours the ventilator has been powered on.

3- BACK LIGHT

Indicates the total accumulated hours the back light has been on. Expected life of the back light is approximately 10,000 hours.

4- DATE

In the lower left corner of the display is a date. This date indicates when the software began tracking elapsed and backlight hours. Because earlier software versions did not track hours, this date is more significant for older units that already have hours on them prior to updating to the software that adds this capability. Since these prior hours are unknown, understand that the hours indicated are the hours starting from this date forward only. Subsequent software upgrades will affect neither this date nor the hours.

5- VER (Version)

Indicates the software version installed.

B- CALIBRATION MENU

This menu is primarily for use by someone skilled in the service and repair of the CROSSVENT-4 Ventilator. Items in this menu that are not listed here are functions designed for maintenance personnel and may be found in the service section of this manual under Performance Checks.

The Calibration Menu allows the Oxygen sensor for the CV-4 to be calibrated for accurate operation. It also allows the entry of the compliance factor of the breathing circuit. The CAL MENU key in the Main Menu is only enabled immediately after turn on and is disabled as soon as any other key, except ALARM QUIET, BACKLIGHT or CONTRAST is pressed. The CAL MENU key is also available in the Test Menu. The Cal Menu will appear on the LCD. It is possible to terminate the calibration mode and return to normal operation at any time by pressing the MAIN MENU key. When returning to the MAIN menu from the TEST or CAL menus, the ventilator may not cycle due to invalid settings caused by changes to those settings made during test or calibration procedures. When the MAIN MENU key is pressed, a reminder to reset parameters is displayed prior to returning to the Main Menu to help avoid this. In either the Main Menu or the Test Menu press the CAL MENU key to enter the Cal Menu.

1- OXYGEN SENSOR CALIBRATION (if sensor is used)

Press the O_2% key. With the O_2 sensor in 21% oxygen (air), allow the sensor to stabilize. Follow the instructions on the Oxygen Calibration Menu. Repeat with 100% oxygen. The microprocessor automatically computes the correction factors necessary to bring the particular fuel cell sensor into calibration.

NOTE: It is important to use the correct reference gases (100 and 21%) when performing this calibration. A worn out sensor will not calibrate accurately.

NOTE: Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

2- COMPLIANCE FACTOR COMPUTATION (use is optional)

The CV-4 automatically utilizes the compliance factor of the patient circuit to compute the volume stored in the patient circuit and the Corrected Volume actually delivered to the patient. The compliance factor for the patient circuit being used may be obtained as follows:

Press COMPLIANCE. Set PEEP to off. Set the Max Pressure knob to maximum to ensure that the ventilator is volume limited. Set a flow of 5 LPM and press enter. A peak pressure of 80-85 cmH_2O will result in the most accurate compliance value using this method. If it reads less than 80 cm. slightly increase the flow setting as the test runs. If it is greater than 85 cm, then lower the flow setting slightly. When two equal and consecutive pressures are read within this range of 80 - 85 cmH_2O, the test will end and display the compliance value.

3- LANGUAGES

Allows for the menus to be displayed in a different language.

4- SET ALL DEFAULTS (see warning that follows)

This key may used to set the default calibration settings for Pressure and Oxygen. It is meant for emergency use only and is provided to allow rapid calibration in the event that it is necessary to calibrate the unit without equipment.

WARNING: THE DEFAULT CALIBRATION MAY NOT BE AS ACCURATE AS THE NORMAL CALIBRATION PROCEDURE. THE NORMAL CALIBRATION PROCEDURE SHOULD BE PERFORMED INSTEAD WHENEVER POSSIBLE.

C- OPERATIONAL TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Fails to respond to touch selection of a key	1.Keys locked 2.Defective touchscreen key	1.Press LOCK key twice to unlock 2.Contact Bio-Med Service Center
Parameter value seems inappropriate	Wrong parameter selected	Select correct parameter
Unit fails to turn on when “ON/OFF” switch is set to on.	1.Battery low and plug-in power supply not connected. 2.No power at outlet and battery low.	1.Plug in charger to active outlet and charge battery 2.Plug into active outlet and charge battery
Internal regulator output pressure varies	Low pressure/flow from gas source; fault in gas supply	Increase gas volume/pressure
Low internal pressure regulator output	1. Output pressure not set; insufficient gas supply 2.Dirty or clogged filter	1.Set output pressure; check gas 2.Service needed
System pressure reads zero and no gas flows out	Gas supply off	Turn on gas supply
Incorrect peak pressure and PEEP/CPAP reading	1.Pressure transducer disconnected or malfunction 2. Pressure transducer is out of calibration	1.Service needed 2. Service needed
Uncontrolled auto-cycle; remains in inspiratory mode	1.Sensitivity setting is too sensitive 2.Pressure transducer malfunction	1.Increase Sensitivity setting 2.Service needed
System pressure reads zero	1.Peak pressure limit control is fully off 2.Tube disconnected between patient and ventilator	1.Adjust the maximum pressure limit control 2.Connect it

V. TESTS, CALIBRATION AND TROUBLESHOOTING- cont.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Peak pressure high limit alarm activates	1.Accumulation of secretion 2.Change in compliance; blockage in airway or tubing 3.Patient tries to breath independently 4.Endotracheal tube has slipped down into a bronchus 5.Change in patient positioning 6.Pneumothorax 7.Sigh	1.Examine patient 2.Remove the blockage or replace the airway/tube 3.Re-evaluate patient status and vent settings 4.Correct the tube position 5.Re-evaluate patient and vent settings 6.Treat patient 7.Set the high alarm limit higher
Peak Pressure Low limit alarm activates	1.Disconnected patient circuit 2.Endotracheal tube has slipped down into a bronchus 3.Water in patient circuit 4.Decrease in lung compliance	1.Reconnect patient circuit 2.Reposition endotracheal tube 3.Empty water from patient circuit 4.Re-evaluate patient
PWI high alarm activates	1.Increase lung compliance 2.Leak in patient circuit or endotracheal tube/cannula	1.Increase alarm limit; re-evaluate patient 2.Check patient circuit connections; adjust the cuff or change endotracheal tube/cannula
Ventilator does not start	1.Power cable not connected and battery discharged 2.Low battery and no power in electrical outlet 3.Blown fuse in plug-in power supply 4.ON/OFF switch in the OFF position	1.Connect power cable; charge or replace battery 2.Change outlet; charge or replace battery 3.Replace transformer 4.Switch to ON
CROSSVENT-4 fails to operate on battery	1.Low battery 2.Missing battery 3.Defective battery	1.Charge battery 2.Insert and attach battery 3.Replace battery
Battery fails to charge properly	1.Plug-in power supply not connected 2.No voltage at outlet 3.Battery “memory” 4.Defective battery 5.Defective charger	1.Connect plug-in power supply 2.Connect to an active outlet 3. Refresh battery 4.Replace battery 5.Replace charger
LOW BATTERY indicator on	Battery discharged	AC power must be restored and battery charged

V. TESTS, CALIBRATION AND TROUBLESHOOTING- cont.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
No exhaled tidal volume reading	1.Pneumotach disconnected 2.Problem with flow channel or differential	1.Reconnect the pneumotach and/or tubes 2.Service needed
Incorrect tidal volume reading	1. Pressure limited 2. Incorrect flow calibration 3. Blocked or kinked pneumotach tubes 4. Leak in patient circuit or endotracheal 5. Inspiratory terminated by Peak Pressure high alarm limit	1. Adjust pressure limit 2. Review flow calibration procedure and recalibrate 3. Check pneumotach tubes and correct blockage 4. Check and correct the patient circuit and endotracheal tube for leaks 5. Adjust Peak Pressure high alarm limit
Incorrect O_2 reading; O_2 gain error message on display	1.O_2 sensor not connected 2.Incorrect calibration procedure 3.Faulty sensor cell	1.Connect sensor 2.Review calibration procedure and recalibrate 3.Replace cell
No O_2 readings	O_2 sensor turned off	Turn on
No temperature readings	Temperature sensor turned off	Turn on

VI. OPERATING INSTRUCTIONS

The following describes the procedure for setting up and operating the CROSSVENT-4 Ventilator. It is assumed that the operator is thoroughly familiar with the Specifications, Theory of Operation, Tests and Calibration procedures as outlined in this manual. It is also assumed that the ventilator is already fully assembled, has been tested and calibrated and is connected to a test lung.

WARNINGS

ONLY QUALIFIED MEDICAL PERSONNEL SHOULD OPERATE THE VENTILATOR.

DO NOT ATTEMPT TO VENTILATE A PATIENT UNTIL THOROUGHLY FAMILIAR WITH ALL OF THE OPERATING INSTRUCTIONS.

THE OPERATING INSTRUCTIONS ARE NOT INTENDED AS RECOMMENDED CLINICAL PROTOCOLS.

ALWAYS TEST THE VENTILATOR PRIOR TO EACH USE. AFTER SET UP, VENTILATE A TEST LUNG TO VERIFY PROPER OPERATION PRIOR TO CONNECTING THE VENTILATOR TO A PATIENT.

IF A MALFUNCTION SHOULD OCCUR, THE UNIT SHOULD BE REMOVED FROM USE AND REPAIRED PRIOR TO USING IT AGAIN ON PATIENTS.

WHENEVER AN ALARM CONDITION EXISTS IT SHOULD BE RECTIFIED IMMEDIATELY. NEVER ALLOW VENTILATION WITH AN ALARM CONDITION FOR AN EXTENDED LENGTH OF TIME.

NOTE: Since it is not possible to damage the CROSSVENT-4 Ventilator by normal use of its keys and control knobs, the user is encouraged to experiment with the CROSSVENT-4 settings while the unit is not connected to a patient.

A- PRELIMINARY STEPS

1- Attach the plug-in power supply output connector to the jack of the ventilator and plug the power supply into an external electrical outlet.

2- Connect a patient circuit to the ventilator. Connect a test lung (BMD #1020 or #1022) to the proximal airway connector.

3- Connect a 50 psi gas supply source to the input connector.

B- DETAILED OPERATING INSTRUCTIONS

1- Turn the ON/OFF switch to the ON position. The unit comes on in the Main menu in the same mode it was in when last used.

2- Press the ALARM QUIET key to increase the temporary audible alarm silence period from 60 sec. to 120 sec. if desired. It may be used as many times as necessary to cancel the audible alarm until the alarm limits are set. The EXT POWER or BATTERY indicator will come on depending on the condition of the power supply. The ventilator will cycle at the rate set on the rate key and the inspiratory source CONTRL indicator will come on during each inspiration. If the ventilator auto-cycles, indicated by ASSIST or SPONT in the Inspiratory Source Window, the inspiratory effort should be increased using the Sensitivity key.

3- Select desired mode, e.g., SIMV.

4- The CROSSVENT-4 primary function keys and control knobs should be set to the desired initial values, for example:

CONTROL	SETTING
RATE	20 BPM
TIDAL VOLUME	700 ml
FLOW (knob)	30 LPM
PEAK PRESS. (knob)	High
PEEP/CPAP (knob)	Zero
SENSITIVITY	1 cmH_2O

NOTE: Reverse field indicates that a parameter has been selected and may be adjusted using the arrow keys.

5- Set the secondary functions - Press the secondary menu key. Press the desired function, which will appear in reverse field. Use the arrow keys to set the desired value.

6- Press the AUTO SET key. It is necessary to press this key twice within 5 seconds in order to activate the auto-limit function. This initiates the automatic computation of high and low limits for all primary alarm parameters.

NOTE: The AUTO SET key should always be used to establish initial limits. These may be used for patient monitoring, in order to facilitate setup or may be set temporarily until "custom limits" are entered to suit specific clinical requirements. Any or all of the limits may then be manually changed.

7- Verify proper operation.

8- Connect the ventilator to the patient.

9- Adjust SENSITIVITY and/or other controls for the particular patient. Observe operating parameters and make fine adjustments.

10- Press AUTO SET. If it is desired to manually change alarm limits, they may now be entered. Press either the Primary or Secondary alarm menu key. Select the desired alarm parameter, e.g., PEAK Pressure. Press the HIGH PEAK PRESS. key. This will appear in reverse field. Use the arrow keys to select the desired value. This sequence of keys, i.e., alarm parameter limit and arrow keys must be used when entering all limits. Once the limit has been entered in memory it may be changed at any time by repeating the sequence.

WARNING: IT IS IMPERATIVE TO VERIFY THAT CLINICALLY APPROPRIATE ALARM LIMITS ARE FULLY OPERATIONAL FOLLOWING CONNECTION OF THE VENTILATOR TO A PATIENT.

WARNING: IT IS IMPORTANT TO NOTE THAT ONCE A SENSOR HAS BEEN TURNED OFF, THE ALARMS FOR THAT SENSOR ARE INOPERATIVE.

NOTE: If it is desired to deactivate the oxygen, temperature or flow sensors, select the desired function, e.g., TEMP. Scroll the lower limit down to OFF. The temperature function is now inoperative. The function may be reactivated at any time by pressing TEMP, and scrolling the low limit up. The TEMP. sensor is now reactivated. This allows the ventilator to be used without the temperature, oxygen and/or flow sensors. When a sensor is off, it may be disconnected while the ventilator is in use, without causing an alarm.

C- SUMMARY OF OPERATING INSTRUCTIONS

1- Turn on.

2- Select mode.

3- Set primary functions in MAIN Menu.

4- Set secondary functions in SECONDARY Menu.

5- Press AUTO SET.

6- Verify proper operation.

7- Connect to patient.

8- Make patient appropriate adjustments to settings.

9- Press AUTO SET and adjust alarm limits if desired.

IMPORTANT NOTES:

1- Flashing I/E Ratio display indicates a timing limit violation and can be permanently silenced only by adjusting the settings to bring them into permissible ranges (also observe Inspiratory and Expiratory times in the VIEW Menu).

2- In Baby mode with CPAP, Auto Shift/Backup is inoperative and nebulizer is inoperative during spontaneous breaths.

VII. CLEANING, STERILIZATION AND PACKING

A- CLEANING AND STERILIZATION

The CROSSVENT-4 Ventilator should be thoroughly cleaned and inspected following each patient use. The entire exterior of the unit should be cleaned with a suitable cleaning agent. During cleaning, power should be turned off and the plug-in power supply should be disconnected. Care should be taken not to allow cleaning agents to enter the unit as this could cause damage and subsequent malfunction.

> **CAUTION:** UNDER NO CIRCUMSTANCES SHOULD THE CROSSVENT-4 UNIT BE GAS STERILIZED, STEAM AUTOCLAVED OR SUBMERGED IN LIQUID. THE COMPONENTS OF THE UNIT ARE INCOMPATIBLE WITH THESE STERILIZATION METHODS AND SEVERE DAMAGE CAN RESULT.

1- Ventilator- The entire unit, with the exception of the LCD touch screen can be cleaned using an appropriate bactericidal or germicidal agent. Care should be used not to allow foreign material, e.g., cleaning agent, pieces of gauze, etc., to enter the unit. Particular care should be taken when cleaning near the connectors and vent screens.

2- LCD Touch Screen Keypad- The touch screen of the CROSSVENT-4 is made of transparent plastic and may be damaged by chemical solvents and abrasive cleaners. Use only alcohol when cleaning this area. Great care should be taken not to touch it with sharp objects, since it may be punctured, which could damage the keys.

3- Patient Circuit- The complete patient circuit supplied with the CROSSVENT-4 is disposable and intended for single use.

4- Re-usable Circuit- The optional Bio-Med Devices re-usable patient circuit may be gas or chemically sterilized as follows:

- Pasteurization at 150° to 170°F (65.6° to 76.6°C) for a minimum of 30 minutes.
- Ethylene Oxide (ETO) cold cycle not to exceed 130° F (54.4° C) with adequate aeration time.

5- Oxygen Tee- The supplied blue oxygen tee may be sterilized with EtO (12%-88% or 100%) gas. Do not exceed 100°F. Aerate for at least 8 hours at 120°F.

B- PACKING FOR SHIPMENT

In the event the CROSSVENT-4 must be returned to the factory, it is very important to pack the unit properly. The following is the correct packing procedure to insure safe transport:

Packing Materials Required:
- Double Wall Carton
- Suitable Shock Absorber - Foam or Air Bubble Wrap
- Poly Bag

Procedure:

1. Cover CROSSVENT-4 with the poly bag and secure with twist tie or tape.

2. Wrap the CROSSVENT-4 in the foam or bubble wrap, with at least 2 inches of material on all sides, and place it into the carton.

3. Wrap oxygen sensor and any other adapters with bubble wrap (if returned).

4. Thoroughly wrap the plug-in power supply with bubble wrap and place it into the carton, making certain that it cannot damage the CROSSVENT-4 while in transit.

5. Place the gas supply hose, if returned, between the rear of the CROSSVENT-4 and the carton wall.

6. Place the patient circuits, pneumotachs, temperature probe and instruction manual in an orderly fashion into the remaining space (if returned).

7. Fill the carton on all sides with packing material to prevent the unit from shifting during transit.

8. Close the carton with tape, noting serial number on the outside of the carton.

9. Ship to:

   BIO-MED DEVICES, INC.
   61 Soundview Road
   Guilford, CT 06437 USA

MAINTENANCE AND SERVICE SECTION

VIII. THEORY OF OPERATIONS

The CROSSVENT-4 is a time cycled, volume or pressure limited ventilator. Its basic principle of operation is extremely simple. Supply gas, either air, oxygen, or a blended mixture, is connected to the CROSSVENT-4 inlet fitting.

NOTE: For blended gas, the Bio-Med Devices blender should be used.

WARNING: When using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

Gas flows first to an internal pressure regulator which provides output gas regulated to approximately 20 psi (see fig. 13). This is used both for patient gas and to set PEEP and maximum pressure levels.

From the regulator the gas flows to a normally closed, 2-way, pilot valve operated by a miniature solenoid valve (valve A). The gas exits the pilot valve and goes to an electronically encoded flow valve. The encoding is accomplished via a precision potentiometer. Since the upstream (supply) pressure is constant and much greater than the downstream (patient) pressure, changes in downstream pressure may be neglected. Therefore, since the supply pressure is accurately regulated, the flow rate becomes a function solely of the flow valve setting. The length of time that gas flows is the inspiratory time. The volume of gas that flows during the on-time is the Tidal Volume and is equal to the on-time (inspiratory time) multiplied by the flow rate.

From here the gas goes into the patient circuit through the patient connector. Pre-set pressure relief valves in the manifold limit the maximum pressure, and allow the patient to draw in ambient air if the entire system becomes inoperative.

During the period of time when valve A is open and gas flows, solenoid valve B is actuated, allowing gas from the Maximum Pressure valve to pressurize the diaphragm of the exhalation valve and the internal diaphragm actuated relief valve (D.A.R.V.). This assures that all gas will flow to the patient. At the end of inspiration, valve A closes and gas flow ceases. Simultaneously, valve B is de-energized, connecting the PEEP valve signal to the exhalation valve diaphragm. This allows the patient to exhale to atmosphere and the pressure in the patient circuit to fall to PEEP or atmospheric pressure.

A low flow flush system is provided to prevent humidity from traveling back up the pneumotach sensing lines (if used) and damaging the pressure transducer.

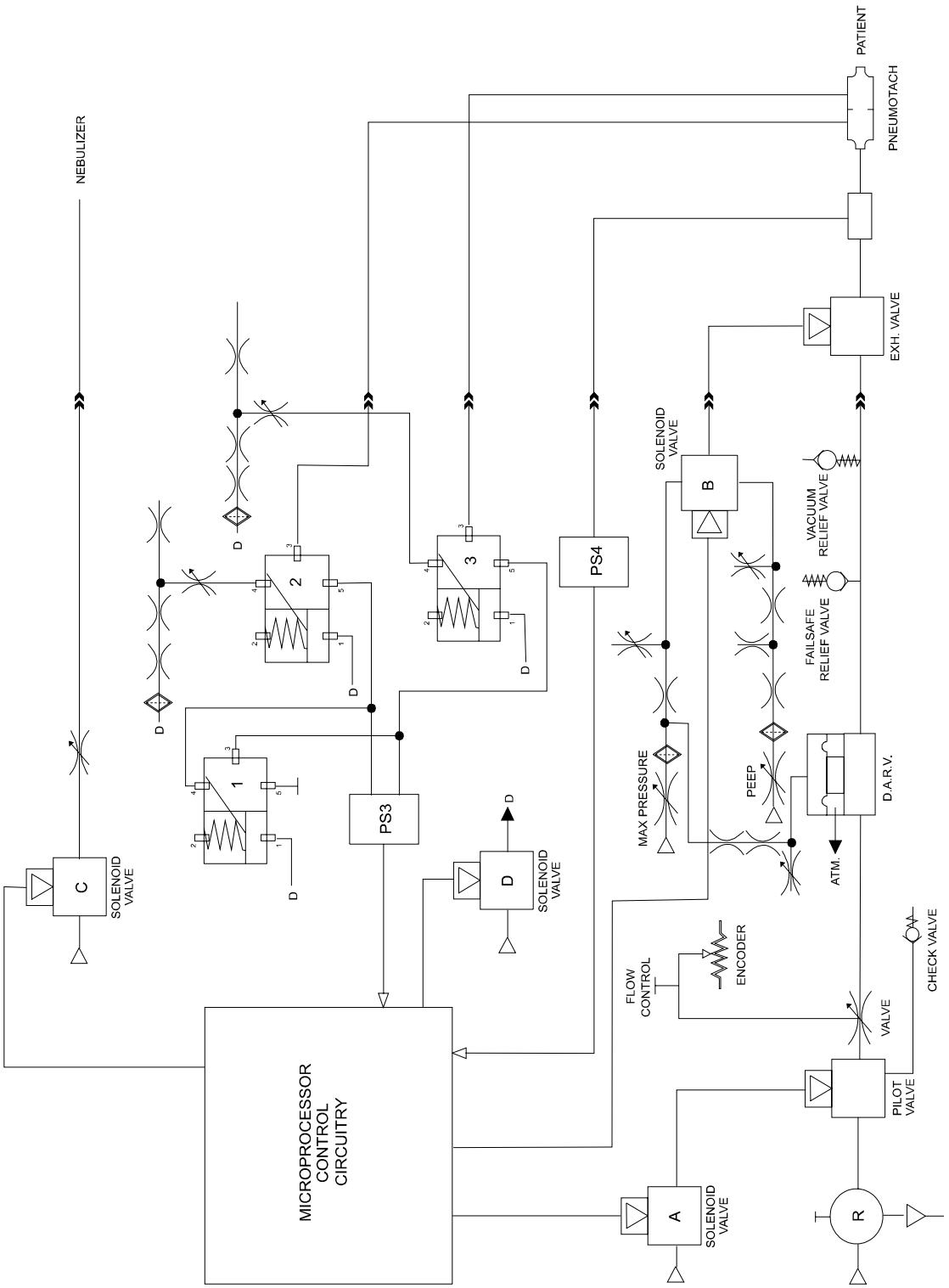


Fig. 13 - SCHEMATIC DIAGRAM

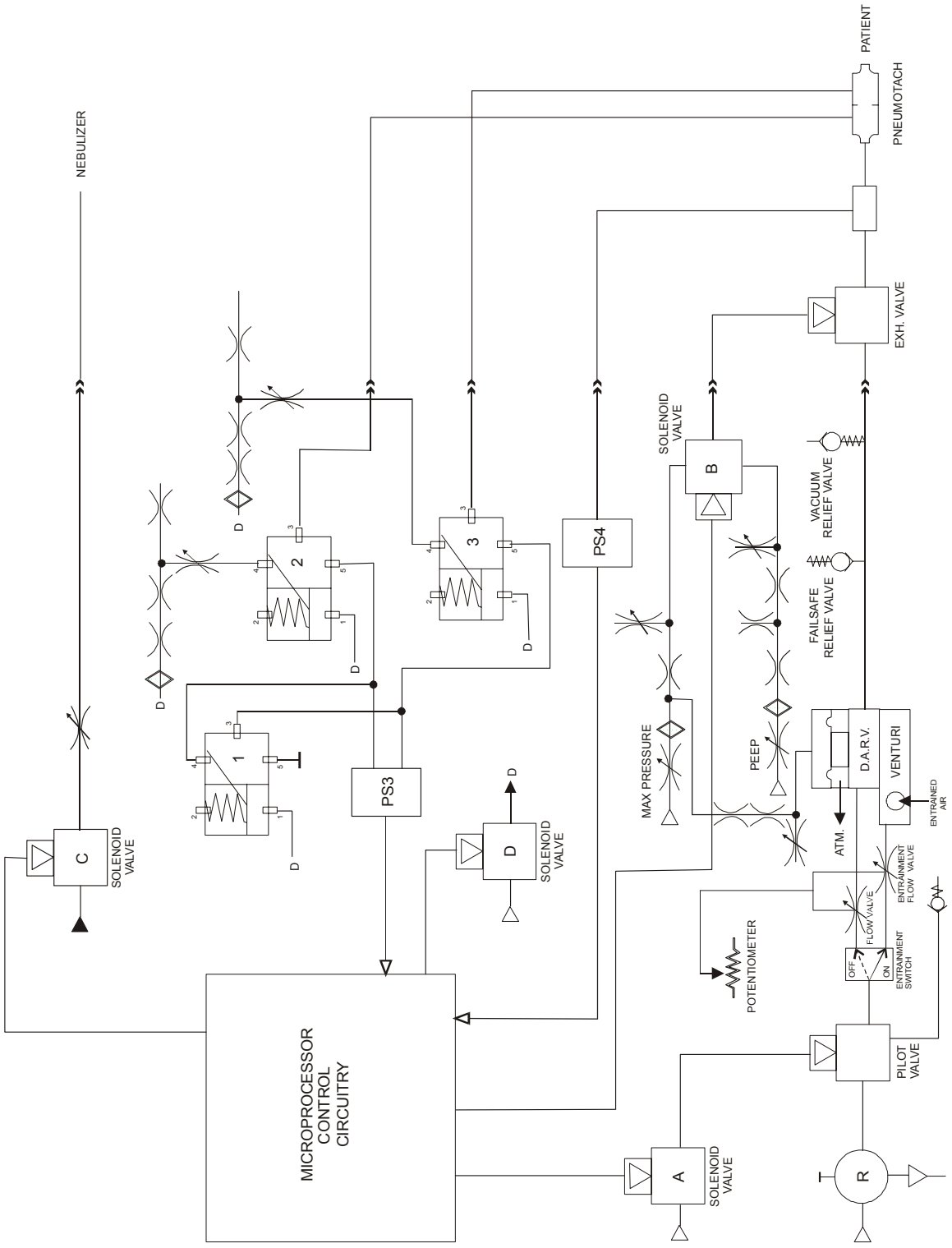


Fig. 13A - SCHEMATIC DIAGRAM with ENTRAINMENT

A- SYSTEM COMPONENTS

Inlet Filter - The supply gas passes through an inlet filter. This filter should be changed periodically. It filters particles down to 40 microns. If equipped with entrainment, there is a second filter in the venturi assembly.

NOTE: It is recommended that an external filter/water trap be used on the supply gas at all times in order to provide greater protection to the internal components of the CROSSVENT-4.

Airway Pressure Transducer - Connected to the proximal airway, the pressure transducer converts the pressure signal into an electrical signal. This electrical signal, which represents the pressure waveform is then used by the CROSSVENT-4's microprocessor to accomplish a multitude of tasks. It is used to sense a pressure drop in the patient breathing circuit created by an inspiratory effort and then provide a trigger signal to initiate inspiration. The transducer output also establishes the levels for the all of the pressure related alarms. It is also used to calculate such parameters as compliance.

Differential Pressure Transducer (optional) - It is utilized to measure the pressure drop across an orifice in a pneumotachograph. The pneumotach is placed at the proximal airway. As exhaled gas passes through the orifice, it creates a pressure drop from one side of the orifice to the other. This small pressure difference is measured by this highly sensitive differential pressure transducer. The signal from the transducer is then converted by the microprocessor into a measurement of exhaled tidal volume and minute volume.

Maximum Pressure Relief Valve - This valve vents gas to atmosphere whenever the pressure in the breathing circuit exceeds the preset level of 120 cmH_2O.

Diaphragm Actuated Relief Valve (D.A.R.V.) - It is controlled by the output signal from the Maximum Pressure needle valve (front panel), which is also applied to the exhalation valve. It sets the relief pressure at approximately the same level as set by the exhalation valve.

Negative Pressure Relief Valve - It allows gas to enter the breathing circuit whenever a negative pressure greater than approximately 4-5 cmH_2O is generated. This acts as a failsafe mechanism and in the event of a total system power failure allows the patient to inhale ambient air.

WARNING: BREATHING THROUGH THIS VALVE REQUIRES A GREATLY INCREASED WORK OF BREATHING AND ONLY AIR IS PROVIDED. A SITUATION IN WHICH THE PATIENT IS BREATHING THROUGH THIS VALVE SHOULD BE RECTIFIED IMMEDIATELY IN ORDER TO PREVENT POSSIBLE ADVERSE AFFECTS TO THE PATIENT.

B- ASSIST CONTROL MODE

In this mode the CROSSVENT-4 will function either as an assist or controller. If the patient is inspiring, the negative pressure created by the inspiratory effort will be sensed by the ventilator and this will initiate an assisted inspiration. If the patient fails to breath, the ventilator will continue to give controlled breaths at the backup rate as set by the main RATE setting.

Inspiration may be initiated by either a patient inspiratory effort or, in the absence of that, the backup setting. At the start of inspiration, gas flows to the patient at the flow rate established by the FLOW control, for the duration of the inspiratory time. Simultaneously, the exhalation valve is pressurized to the Maximum Pressure level. The maximum pressure attainable is established by the MAXIMUM PRESSURE control on the front of the ventilator. At the end of the inspiratory time, the patient gas flow is terminated and zero or PEEP pressure is applied to the exhalation valve. If plateau is on, Maximum Pressure will be maintained for an additional period of time equal to a percentage of the inspiratory time as set by the PLATEAU setting. At the end of this plateau period, the patient circuit pressure is allowed to fall to the PEEP level as set by the PEEP control on the front of the ventilator, thus allowing the patient to exhale. This allows the pressure in the patient circuit to fall only to the PEEP level.

The SIGH function can only be used in the Assist Control and SIMV modes. During a SIGH breath, the patient gas and Maximum Pressure remain on long enough to deliver the SIGH volume at the preset normal flow rate. This is equivalent to 1.5 times the volume set while the I/E ratio of a sigh breath is maintained at the same I/E ratio of a normal breath as set with the three primary controls: RATE, TIDAL VOLUME and FLOW.

The End Inspiratory Plateau is not functional during a sigh breath. If the plateau is turned on when a sigh breath is given, the ventilator automatically cancels the plateau during the sigh breath.

C- SIMV (Synchronized Intermittent Mandatory Ventilation) MODE

In the SIMV mode, the CROSSVENT-4 delivers two main types of breaths: ASSISTED and SPONTANEOUS. Both are initiated by the patient's inspiratory effort, which is sensed by the ventilator. The assisted breaths are the same as assisted breaths in the Assist Control mode. The rate of administration of assisted breaths is set using the SIMV RATE key and entering the desired value.

In between the assisted breaths, patient inspiratory efforts initiate spontaneous breaths. When the ventilator detects an effort to breath, it initiates inspiration and delivers gas to the patient at a rate determined by the FLOW control and for a period of time equal to the inspiratory time of a normal assisted breath.

The difference between a spontaneous and assisted breath is that during a spontaneous breath, Maximum Pressure is not applied, only the PEEP pressure signal is applied to the exhalation valve, thus delivering gas to the patient at zero or PEEP pressure, if PEEP is on.

The full tidal volume is made available at the proximal airway. Whatever gas is not inspired by the patient is vented to atmosphere. At the end of the inspiratory time, should the patient desire a greater tidal volume than that which is set, he need only continue to inhale. As long as pressure below baseline (zero or PEEP) is detected, the ventilator will continue to deliver boluses of gas as determined by the TV setting. The patient is free to trigger as many spontaneous breaths as needed between assisted breaths. At the end of the time interval established by the SIMV RATE control, the ventilator administers an assisted breath, synchronized to the patient's breathing effort.

Pressure Support: When pressure support is turned on, the patient circuit pressure is allowed to increase above baseline (zero or PEEP) by the number of cmH_2O as set by PRESSURE SUPPORT. This occurs only during spontaneous breaths. When the airway pressure reaches the pressure support level, the baseline pressure is restored, allowing the exhalation valve to open, but the patient gas continues to flow for the duration of a normal assisted breath as set by the RATE and TIDAL VOLUME controls.

WARNINGS: IT IS EXTREMELY IMPORTANT THAT THE SENSITIVITY CONTROL BE CAREFULLY ADJUSTED TO ASSURE PROPER OPERATION IN THE SIMV MODE. ALSO, UNDER CERTAIN CONDITIONS IN SIMV WITH PEEP, EVEN THOUGH THE LOW PEAK PRESSURE ALARM IS SET CORRECTLY FOR ASSISTED BREATHS, THERE MAY BE NO LOW PEAK PRESSURE ALARM FOLLOWING A PATIENT DISCONNECT UNTIL THE NEXT ASSISTED BREATH. (THIS PERIOD MAY BE UP TO 2 MINUTES.) AS AN ADDED PRECAUTION, SET THE LOW PEEP/CPAP AND LOW EXHALED TIDAL VOLUME ALARMS SO THAT THEY ARE OPERATIVE.

D- CPAP (Continuous Positive Airway Pressure)

In the CPAP mode, the breaths are delivered in exactly the same manner as a spontaneous breath in the SIMV mode. Each breath is triggered by the patient's inspiratory effort. Gas flows to the patient for a period of time equal to the inspiratory time of a normal assisted breath (established with the Tidal Volume and Flow controls). The flow rate during a CPAP breath is set with the Flow control. During CPAP breaths, Maximum Pressure is inactive and the gas is delivered at zero or CPAP pressure. The full volume is made available at the proximal airway, with additional boluses available with continued effort until the patient is satisfied. Whatever gas is not inspired by the patient is vented to atmosphere.

Pressure Support: See SIMV above.

WARNING: IT IS EXTREMELY IMPORTANT THAT THE SENSITIVITY CONTROL BE CAREFULLY ADJUSTED TO ASSURE PROPER OPERATION IN THE CPAP MODE.

WARNING: UNDER CERTAIN CONDITIONS IN CPAP, IN PARTICULAR WITH HIGH FLOWS AND LOW CPAP PRESSURES, IF THE LOW PEAK PRESSURE ALARM IS SET SO THAT NO FALSE ALARMS OCCUR, THIS ALARM MAY BE INOPERATIVE IF A DISCONNECT OCCURS. IT IS THEREFORE EXTREMELY IMPORTANT TO HAVE THE LOW PEEP/CPAP AND LOW EXHALED TIDAL VOLUME ALARMS SET CORRECTLY.

E- AUTO SHIFT AND BACKUP MODALITIES

These modalities establish the response of the CROSSVENT-4 in the event of patient apnea. In both the SIMV and CPAP modes, either the BACKUP or AUTO SHIFT modality may be selected using the AUTO SHIFT key. When AUTO SHIFT is off, the unit is in the Backup Modality and provides a backup breathing rate established with the BAKUP RATE control. This assures a minimum breathing rate. This backup rate operates any time the patient's spontaneous breathing rate falls below the backup rate. It does not, however, eliminate the possibility of using very low SIMV rates. As long as the patient's spontaneous breathing rate is above the backup rate, the backup timer is locked out and no control breaths are administered. No apnea alarm is sounded for control breaths. This modality in conjunction with the exhaled minute volume alarm, thus provides a guaranteed Minimum Minute Ventilation (MMV) established with the rate and tidal volume controls. It is therefore possible to always ventilate every patient in the SIMV mode, if desired, since a Minimum Minute Ventilation (MMV) is guaranteed, even if the patient becomes apneic.

Setting AUTO SHIFT to on provides for automatic mode change operation. In this modality the ventilator waits a selectable period of time, set using the AUTO SHIFT key and UP and DOWN Arrows. If the patient has not initiated a breath within this period, the ventilator switches to the Assist Control Mode and sounds an alarm. The ASIST CNTRL indicator will flash. The audible alarm may be temporarily silenced for 60 sec. by pressing alarm quiet. The alarm will be permanently canceled and the flashing of the indicator will be stopped by pressing any of the three mode buttons. Whenever either SIMV or CPAP are pressed and the patient is still not breathing spontaneously, at the end of the mode change delay period the ventilator will always shift to the Assist Control mode again and sound the alarm. The alarm may be silenced by pressing ASIST CNTRL.

WARNING: IT IS IMPORTANT IN BOTH MODALITIES TO ALWAYS SET A CORRECT RATE, TIDAL VOLUME AND FLOW TO INSURE PROPER VENTILATION IN CASE THE PATIENT BECOMES APNEIC.

IX. MAINTENANCE AND SERVICE

WARNINGS: Technical repairs should be performed by qualified personnel, trained either by BIO-MED DEVICES, INC or their authorized trainers. Bio-Med Devices, Inc. is not responsible for unauthorized repairs, or repairs made by unauthorized procedures.

The CV-4 should pass a full technical performance check after any repair procedure that requires the case to be opened.

All safety measures must be observed when servicing this device. In particular, the ventilator must be turned off and the power supply disconnected.

Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

A- TEST & CALIBRATION MENU OVERVIEW

The following is an overview of the TEST and CALIBRATION (CAL) menus. Some functions in these menus will be used in the performance checks that follow this overview.

WARNING

ONLY QUALIFIED, TRAINED, SERVICE TECHNICIANS SHOULD ATTEMPT REPAIRS AND SERVICE WHEN NEEDED. SERIOUS PERSONAL INJURY AND/OR EQUIPMENT DAMAGE CAN RESULT IF REPAIRS ARE PERFORMED BY UNQUALIFIED PERSONNEL.

In the Test mode the microprocessor will run through a series of pre-programmed, self-diagnostic routines (self-test), which enable the user to ascertain that different components of the microprocessor and other CROSSVENT-4 subsystems are functioning properly. This mode is primarily for use by someone skilled in the service and repair of the CROSSVENT-4 Ventilator.

To activate the test mode, turn the ON/OFF switch to ON and press the TEST key on the main menu. This key is only enabled immediately after turn on and is disabled as soon as any other key, except ALARM QUIET, BACKLIGHT or CONTRAST, is pressed. The test menu will appear on the LCD and the alarm LED will turn on and turns off when any other key is pressed. It is possible to terminate the test mode and go to the CAL menu by pressing the CAL MENU key or return to normal operation at any time by pressing the MAIN MENU key.

1- KEYS Touch Screen Test

Displays the Key Test menu. Each key is numbered (1 to 63). It is used to determine that all touch screen keys are operating properly. When a key is pressed it will change to reverse field. When pressed again it changes back. Each key may be toggled as many times as necessary. Press the TEST MENU key to end this test and return to the Test Menu.

2- RAM (Random Access Memory) Test

During this test the current address being tested is displayed. If an error is detected a ”FAIL” message will be displayed. If no error is detected, a “PASS” message will be displayed.

3-ROM (Read Only Memory) Test

While testing the current address is displayed. If an error is detected a “FAIL” message will be displayed. If no error is detected, a “PASS” message will be displayed.

4- DISPLAY (LCD) TEST

Tests all pixels by gradually changing all pixels from light to dark. When it’s done, it returns automatically to the Test Menu.

5- FLOW TEST (CALIBRATION) *Accessible only with security code*

Allows for the calibration of the flow of patient gas as set by the Flow Valve on the front of the Crossvent. Flows are set and the flow value displayed here is compared with the actual flow being delivered as measured by a test instrument.

6- VALVES

May be used to activate the internal solenoid valves independently for calibration and troubleshooting purposes.

VALVE A - PILOT VALVE
VALVE B - SIGNAL PRESSURE TO EXHALATION VALVE
VALVE C - NEBULIZER
VALVE D - PNEUMOTACH FLUSH

7- LEAKAGE

Tests the integrity of the patient circuit and its connections.

8- ELAPSED HOURS

Indicates the total accumulated hours the ventilator has been powered on.

9- BACK LIGHT

Indicates the total accumulated hours the back light has been on. Expected life of the back light is approximately 10,000 hours.

10- DATE

In the lower left corner of the display is a date. This date indicates when the software began tracking elapsed and backlight hours. Because earlier software versions did not track hours, this date is more significant for older units that already have hours on them prior to updating to the software that adds this capability. Since these prior hours are unknown, understand that the hours indicated are the hours starting from this date forward only. Subsequent software upgrades will affect neither this date nor the hours.

11- VER (Version

Indicates the software version installed.

CALIBRATION (CAL) MENU OVERVIEW

The Calibration Menu allows the sensors of the CV-4 to be calibrated for accurate

operation. It also allows the entry of the compliance factor of the breathing circuit. The CAL MENU key in the Main Menu is only enabled immediately after turn on and is disabled as soon as any other key, except ALARM QUIET, BACKLIGHT or CONTRAST is pressed. The CAL MENU key is also available in the Test Menu. The Cal Menu will appear on the LCD. It is possible to terminate the calibration mode and return to normal operation at any time by pressing the MAIN MENU key. When returning to the MAIN menu from the TEST or CAL menus, the ventilator may not cycle due to invalid settings caused by changes to those settings that were made during test or calibration procedures. When the MAIN MENU key is pressed, a reminder to reset parameters is displayed prior to returning to the Main Menu to help avoid this. In either the Main Menu or the Test Menu press the CAL MENU key to enter the Cal Menu.

1- PRESSURE TRANSDUCER CALIBRATION (***Accessible only with security code)***

Used to calibrate the pressure transducer for accurate display of airway pressure.

NOTE: After pressing the default key, it is important to then perform the zero pressure calibration as outlined in this paragraph.

WARNING: THE DEFAULT CALIBRATION MAY NOT BE AS ACCURATE AS THE NORMAL CALIBRATION PROCEDURE. THE NORMAL CALIBRATION PROCEDURE SHOULD BE PERFORMED INSTEAD WHENEVER POSSIBLE.

2- OXYGEN SENSOR CALIBRATION (if sensor is used)

This function is used to calibrate the Oxygen sensor cell.

NOTE: It is important to use the correct reference gases (100 and 21%) when performing this calibration. A worn out sensor will not calibrate accurately.

NOTE: Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

3- COMPLIANCE FACTOR COMPUTATION (use is optional)

The CV-4 automatically utilizes the compliance factor of the patient circuit to compute the volume stored in the patient circuit and the Correct Volume actually delivered to the patient. The compliance factor for the patient circuit being used may be automatically calculated here.

4- LANGUAGES

Allows for the menus to be displayed in a different language.

5- SET ALL DEFAULTS

This key may used to set the default calibration settings for Pressure and Oxygen. It is meant for emergency use only and is provided to allow rapid calibration in the event that it is necessary to calibrate the unit without equipment.

WARNING: THE DEFAULT CALIBRATION MAY NOT BE AS ACCURATE AS THE NORMAL CALIBRATION PROCEDURE. THE NORMAL CALIBRATION PROCEDURE SHOULD BE PERFORMED INSTEAD WHENEVER POSSIBLE.

B- PERFORMANCE CHECKS

WARNING: If the CV-4 fails any of the following performance checks, remove the unit from patient service and submit for maintenance.

TEST MENU

Turn on the unit and press the TEST key.

KEYS

Press the KEYS button. Press each key area noting each key will go to reverse video as well as sound a tone. If any key fails this test, submit for service. Push TEST MENU to return to the TEST Menu.

RAM

Press the RAM button. If the RAM check is good, PASSED will be displayed.

ROM

Press the ROM button. The word TESTING will appear. After test is complete, the word PASSED will be displayed.

DISPLAY

Press the DISPLAY button. The screen will go clear and then slowly scroll into reverse video. This will occur three times. You should not see any clear pixels in the reversed video area.

FLOW VERIFICATION

NOTE: For greatest accuracy, verify flow using a 60% O2 gas supply, (100% O_2 with Entrainment on,) making certain that the pressure to the CV-4 inlet remains within specified pressure limits (44-66 psi; 303.6 – 455.4 kPa*) at all flows.*

Remove the exhalation valve from the patient hose. Turn Max Pressure on fully, make certain that the proximal airway pressure line and the pneumotach (if so equipped) are connected. Connect the patient hose to a certified flow measurement instrument. After turning ON the CV-4, press the TEST key, select VALVES and turn on Valve "A".

1. With the supply pressure maintained as defined in the preceding *NOTE*, turn the Flow Knob to its maximum setting and verify the flow indicated by the test instrument is 108 - 132 LPM.
2. After verifying step 1, adjust the flow knob to various flow levels, some high and some low, and verify that the flow displayed in this menu is within ±10% of the actual flow as indicated by the test instrument.

LEAKAGE

Connect the patient circuit with a test lung to the Crossvent. Set the Max Pressure to its maximum setting. Set the PEEP to its maximum setting. Set the flow control to 10 LPM. Press enter. The Crossvent will pressurize the system and indicate "TESTING", followed by either "PASSED" or "FAILED" depending on the results. If it fails the test, check the patient circuit and all connections, and retest.

NEBULIZER FLOW (Valve C)

Connect nebulizer port to high flow monitor and turn on CV-4.

Go to TEST menu and activate VALVES.
Turn ON valves A and C with a flow of 40 LPM.
Nebulizer flow should be between 6.5 - 7.5 LPM.

FLUSH (Valve D- if equipped with Exhaled Tidal Volume monitoring)
Connect patient distal port to low flow test standard and turn ON CV-4.
Go to TEST menu and activate VALVES.
Turn ON valves A and D with a flow of 40 LPM.
Check for distal flow of 40 - 60 ml/min.
Repeat for proximal port.

RELIEF VALVE (Valve A)
Install a patient circuit on the CV-4 and occlude the end.
Tee a low pressure measurement instrument into the airway pressure line.
Turn on the CV-4 and press TEST.
Turn on Valve A.
Occlude the exhaust port of the exhalation valve on the circuit and slowly increase the MAX PRESS Knob (CW) until it is fully open.
Slowly increase the flow by turning the Flow Knob clockwise until it is fully open.
The Relief Valve should begin to relieve around 110 cmH2O, not exceeding 144 cmH2O.

CALIBRATION (CAL) MENU
If in the TEST Menu, press the CAL key, otherwise turn the unit off and back on and press the CAL key.

OXYGEN TEST

NOTE: Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

With an O2 Sensor installed to the CV-4 and open to atmosphere, turn the CV-4 on.
Push the CAL button and then the OXYGEN Button.
Wait 3-4 minutes and then Push the 21% Button.
Install the O2 sensor into the Patient Circuit and with 20cm of PEEP and 5 LPM flow, apply 100% Oxygen. Wait 3-4 minutes and then Push the 100% button.
Percentage of O2 checks may now be made using a calibrated O2 blender or Test Set.

COMPLIANCE
Press COMPLIANCE.
Set PEEP to off.
Set the Max Pressure knob to maximum to ensure that the ventilator is volume limited.
Set a flow of 5 LPM and press enter.
A peak pressure of 80-85 cmH_2O will result in the most accurate compliance value using this method. If it reads less than 80 cm. slightly increase the flow setting as the test runs. If it is greater than 85 cm, then lower the flow setting slightly.
When two equal and consecutive pressures are read within this range of 80 - 85 cmH_2O, the test will end and display the compliance value.

PRESS THE MAIN MENU KEY TO EXIT THE CALIBRATION MENU

BAR GRAPH ACCURACY

Disconnect the patient circuit.
Tee the airway pressure fitting on the side of the Crossvent to a low-pressure measurement instrument and a 10-25 ml syringe (or similar).
Turn on the CROSSVENT in the MAIN menu and set:
RATE to 20
TV ml to 500
FLOW to 15
In the ALARM 1 menu, set the PEAK PRESS Alarm high limit to its maximum setting
In the ALARM 2 menu, set the PEEP alarm high and low limits to their maximum settings.
As the unit cycles, slowly depress the plunger on the syringe. Stopping at various pressures along the bar graph, verify the readings on the bar graph are within ±10% of the readings on the test instrument.

PEEP PRESSURE SIGNAL

Connect the Exhalation Valve fitting on the side of the Crossvent to a low pressure test instrument.
With the PEEP Knob fully clockwise, the pressure reading should be 15-20 cmH_2O.

FAIL-TO-CYCLE (FTC) ALARMS

Turn on the CV-4 for a minimum of 5 minutes and set the following:
RATE to 150
TVml to 1900
FLOW to 0
Turn the CV-4 OFF and then ON.
Push QUIET once resulting in a 120 sec. audible alarm silence.
The Alarm Light (LED) should be flashing.
The FTC Audible Alarm should occur within 36 - 44 sec and LED should flash.
Push ALARM RESET on the left side of the ventilator to quiet the audible alarm. This should silence the FTC alarm for 54 - 66 sec. after which it should again be audible.
The LED should continue to flash.
Reset the RATE, TV and FLOW to Normal settings (Rate- 20, TV- 500, Flow- 30).

BATTERY ALARM (notifies the user they are in battery mode)

Turn on the CV-4 without external power.
BATT window will flash along with flashing LED.
The audible alarm is silenced for 60 seconds when unit is initially powered on.
Press the BATT key to acknowledge battery mode and to cancel the Battery Alarm.
NOTE: If a period longer then 60 sec passes before pushing BATT key, the audible alarm will sound. When the BATT key is eventually pushed, the alarm will be canceled.
BATT key will revert to 5-segment bar graph indicating percentage of battery charge

left.

EXTERNAL POWER FAILURE ALARM
Connect the Bio-Med Devices Crossvent Power Supply to the power input on the side of the Crossvent.
With the CV-4 turned ON, EXT POWER will appear in the lower left of the display.
After 1 minute of operation, remove External Power.
EXT POWER will change to a flashing BATT, the LED will flash and the audible alarm will sound.
Press BATT to stop the alarm.
The BATT key will revert to the 5-segment bar graph indicating the percentage of battery charge left.

POWER FAILURE ALARM (CV-4 turned off)
With the CV-4 operating for a minimum of 5 min., turn the CV-4 off with the On/Off Power Switch.
The LED will flash along with an audible alarm.

Test 1: The LED and audible alarm should continue for 3 min.

Test 2: Repeat this test and push ALARM RESET to stop the audible alarm. The LED should continue to flash for 3 min.

ALARM QUIET
With the CV-4 cycling (longer than 1 min), cause the unit to alarm, i.e., remove the patient circuit. The audible alarm should sound along with a flashing LED.
Press the ALARM QUIET key and verify that the alarm silences for 60 sec.
Press the ALARM QUIET key twice and verify that the alarm silences for 120 sec.

BACKLIGHT
Press the middle of the Pressure Bar Graph and verify that the BACKLIGHT turns ON and OFF in battery mode only.

CONTRAST
Press and hold the PEAK area above the Pressure Bar Graph and verify that the display contrast decreases.
Press and hold the PEEP area below the Pressure Bar Graph and verify that the display contrast increases.

LOCK
Press LOCK and verify that all functions except BACKLIGHT, CONTRAST, MENU KEYS, and ALARM QUIET are locked out.
Press LOCK twice to unlock.

TEMPERATURE CHECK (ALARM 2 MENU)
Turn ON the CV-4 and press the ALARM 2 Menu key.
Turn ON TEMP.
Select and Install Test Adapter (Bio-Med Devices Part #PRT4440) into the Temp Jack and read the following ±5%:

100KOHM = 25 deg C/ 77 deg F

73.2KOHM = 31.9 deg C/ 89.4 deg F

NOTE: USE THESE SETTINGS FOR THE FOLLOWING TESTS UNLESS OTHERWISE NOTED:
RATE = 20 bpm
TV = 500 ml
FLOW = 30 LPM

ASSIST CONTROL FUNCTIONS (SET TO Assist Control MODE)

SIGH (SEC MENU)
Connect the patient circuit to a test standard and measure inspiratory time.
Activate SIGH and verify the inspiratory time increases by 1.5 times.
Deactivate SIGH and measure the expiratory time.
Activate SIGH and verify the expiratory time increases by 1.5 times.
Increase the rate to 100 bpm and verify a Sigh Breath is delivered every 100 breath.

NEBULIZER (SEC MENU)
Insert a Nebulizer in the CV-4 patient circuit and connect the output of the patient circuit to a flow monitor.
Cycle the CV-4 and measure the volume delivered.
Activate NEBULIZER and verify that the volume remains the same and that the I:E ratio changes.
With the NEBULIZER still ON, decrease the Crossvent FLOW to < 20 LPM and verify that the nebulizer flow ceases and indicates DISABLED.

PLATEAU (SEC MENU)
Connect the Exhalation Valve port on the left side of the Crossvent to a Pressure-Timing Test Standard and cycle the unit.
Observe the length of time the Max Pressure signal is present.
Activate PLATEAU and set it to 33%.
Verify that the length of time of the Max Pressure signal increases by 33%.

AUTO SET
Connect a patient circuit with a test lung, O2 sensor and temperature probe to the CV-4.
Turn the CV-4 ON, in the ALARM 1 Menu turn ON O2, in the ALARM 2 Menu turn ON TEMP.
Return to the ALARM 1 Menu.
While the CV-4 is cycling, press AUTO SET twice and verify that after 5 breaths the following occurs: High Rate =+30%, Low Rate = 0; High and Low Peak Press = ±30%; O2 = ±5; High Temp = 40 deg C. Repeat in CPAP and verify low CPAP = CPAP less 3 cmH2O, high CPAP = CPAP plus 3 cmH2O, TEMP and O2 remain the same as above.

RATE
Connect a patient circuit to a Rate Test Standard and cycle the Crossvent.
Set Various RATE settings and verify that delivered rates are within 10%.

TIDAL VOLUME
Connect the patient circuit to a Tidal Volume Test Standard
Turn on the CV-4 and set the Max Pressure knob fully CW.
Set the TV to 200 and Flow to 20 and verify delivered Tidal Volume is within 10%.
Repeat for TV 500, Flow 30; TV 1000, Flow 60; TV 2000, Flow 80.

SIMV FUNCTIONS (SET TO SIMV MODE)

BACKUP RATE
Turn ON the CV-4, turn OFF AUTO SHIFT (SEC menu) if ON.
Connect the CV-4 to a Rate Test Standard.
With the BACKUP RATE set to 20 and without initiating a breath with effort, verify the unit delivers controlled breaths at the set rate.

PRESSURE SUPPORT (MAIN MENU)
Set PRESSURE SUPPORT to 10 cm and initiate breaths using inspiratory effort. Verify that the high-pressure signal to the exhalation valve is terminated when the circuit pressure equals 10 cm above PEEP during spontaneous breaths only, and that the gas flow remains on for the duration of the set inspiratory time.

AUTO-SHIFT (SEC MENU)
Set AUTO SHIFT to 10 sec and verify that the CV-4 shifts to Assist Control and alarms if no breath is initiated by effort for 10 seconds.

SENSITIVITY (MAIN MENU)
Tee a calibrated low-pressure analog gauge into the airway pressure line of a patient circuit.
Remove the test lung and install a patient filter onto the circuit.
Set Sensitivity to -1.0 cm and verify the CV-4 triggers a breath when a pressure of -1 cm is applied to the circuit.
Repeat for -5 cm.

SIMV RATE (MAIN MENU)
Connect the exhalation valve port to a Pressure Transducer and Oscilloscope and Syringe to airway pressure port.
Set TV and FLOW so an INSP of 1 sec is delivered (IE TV = 250, FLOW = 15).
Set the SIMV Rate to 1.0 and using syringe create and hold enough negative pressure to lock CV-4 in Auto-Cycle.
Verify the interval in seconds between assisted breaths is 60 sec ±10%.
Repeat for 6.0 (10 sec) and 30 BPM (2 sec).

BABY MODE
With FLOW set <30 LPM, turn on BABY Mode and verify flow remains ON.
With BABY Mode on, increase Flow to ≥30 LPM and verify that the alarm sounds and the FLOW window flashes.

CPAP FUNCTIONS (SET TO CPAP MODE)

MANUAL
Press the MANUAL key and verify a pressurized breath is delivered and MAN is displayed in the lower left during this breath.

SENSITIVITY
Same as SENSITIVITY test in SIMV.

ALARM 1 MENU
Exceed each limit, HIGH and LOW, in the menu and verify the CV-4 alarms. Verify that the alarms, used optionally, can be turned OFF.

ALARM 2 MENU
Same as ALARM 1 MENU.

C- RECOMMENDED TOOLS AND TEST EQUIPMENT

Special Tools and Test Equipment

Items available from BMD

Part Number	Description
1020	Test Lung
80011	Patient Circuit
2002K	O2 Blender
PRT4440	Temperature Test Plug

Items NOT available from BMD

Item	Description
Anti-Static Cable	Anti-Static mat ground cable ass'y.
Anti-Static Mat	Workbench cover
Anti-Static Strap	Wrist Strap
Digital Voltmeter	Mulitimeter
Syringe and tee	25 or 50 ml. with .170" barb tee
DC Power Supply	0- 30 VDC @ 2A min.
Pressure Transducer	-30 to +140 cmH20
Pressure Standard	-30 to +140 cmH20 ±0.5 cmH2O
Temperature Standard	80 to 110 degrees F; ±0.2 deg. F
Oxygen Analyzer	21 to 100 %; ±1%
Oscilloscope	100 MHz, Storage

Common Tools

Item	Description
Allen Hex Drivers	Up to 5/32"
Diagonal Cutters	
Hemostat	4" or similar
Needle Nose Pliers	
Screw Driver	Assorted
IC Puller	Standard in-line
IC Puller	PLCC type

D- PREVENTATIVE MAINTENANCE

Periodic preventive maintenance should be performed to insure continued proper operation of the CROSSVENT-4 Ventilator. The frequency of preventative maintenance is determined by many factors, some of which are:

* Frequency & length of use
* Quality of the compressed gas source(s)
* Environmental conditions

The following is a list of routine maintenance procedures and maintenance schedule.

BIO-MED DEVICES, INC.
61 Soundview Road
Guilford, CT 06437 USA
800-224-6633 (800-2BIOMED)

Recommended Maintenance Schedule

Interval	Recommended Procedures
Prior to each use	Check battery condition Self Test
Periodic	Performance Check as shown below Refresh battery
Every 2 years or 10,000 hr, whichever comes first	Major overhaul, cleaning and calibration Backlight replacement. Battery replacement* **Recommend return to factory for this service**
6 years	Replace PC Board

***Replace only with batteries supplied by Bio-Med Devices, part # PRT4402. Do not substitute.**

Note: Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

Gas Inlet Filter

The filter element in the supply inlet fitting (DISS O_2 Input) should be replaced during major overhauls or whenever it becomes clogged.

Battery Check

The battery should be checked before each use. To check:

Turn on the CV-4 and remove the external power supply connector. The ventilator should continue to operate correctly. The Power Source window should display "BATT" and the audible alarm should sound. Pressing the Power Source window should permanently silence the audible alarm. Restoring the external power should cause the Power Source window to show "EXT POWER". If a battery operation alarm does not sound when AC power is lost or if the unit fails to operate on battery, the unit should be removed from service and tested.

One minute after turn-on observe the battery bar graph. If bar graph shows less than 50% charge remaining, (approx. 6 hrs without back light operation), put the CV-4 on

charge. Recheck in 6 hrs. If the battery condition has not improved, remove the CV-4 from service for battery reconditioning (refer to Section III, Part C-3) or replacement.

Preventive Maintenance Parts Kits

Part Number PRT4448 -	Units with Exhale Tidal Volume monitoring option only.
Part Number PRT4449 -	Units without Exhale Tidal Volume monitoring option only.
Part Number PRT4450 -	Entrainment units with Exhale Tidal Volume monitoring option only.
Part Number PRT4451 -	Entrainment Units without Exhale Tidal Volume monitoring option only.

Included in the kits are the following parts: Filter, MAX/DARV Pressure Line, PEEP Pressure Line, Nebulizer Line, Flush Line (PRT4448/4450 only). Additionally recommended parts to replace are the Battery, Flow Valve, MAX Pressure Valve, and PEEP Pressure Valve if the clear tubing off the regulator shows any contamination or discoloration inside it. A slightly cloudy look to the large clear tube from the regulator to the flow valve may be normal for this tubing. The small, clear tubes should be clear, however.

To replace the filter:

1. Remove the Rear Panel. (Be careful of the battery which is now free).
2. Remove the Bleed Manifold screws and move the manifold off to the side.
3. Hold the regulator mount with a 3/4" wrench.
4. Using a second 3/4" wrench, remove the O_2 supply fitting on the side of the Crossvent.
5. Replace the old filter with the new filter and reassemble in the reverse order.
6. Entrainment - In addition, remove the black bezel from the venturi assembly and replace the filter inside. Reinstall the bezel.

To replace the logic lines:

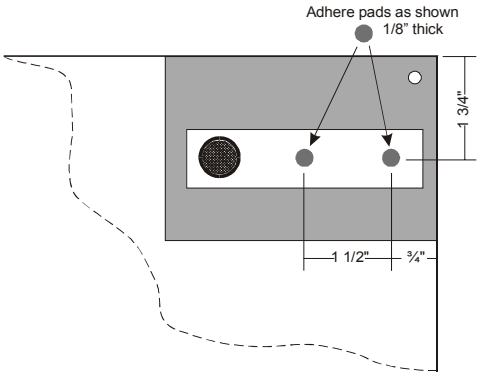
1. CAREFULLY cut the line to be replaced from the barbs at its ends. Take extreme care not to damage the barbs.
2. Remove the old line.
3. Install the new line in the same orientation as the old line and fully push it's ends onto the appropriate barbs. Take care to ensure that all fittings and pneumatic resistors are unable to touch the PC Board.
4. Refer to the calibration procedures for each line replaced.

To replace the battery:

CAUTION: Only replace the battery pack with Bio-Med Devices part #PRT4402. Do not substitute. The cells are non-standard high capacity cells.

1. Lay the unit down on its front and remove the four screws in the corners of the rear panel. Remove the rear panel.
2. Lift the battery out of the battery enclosure and unplug the battery connector.
3. Verify four 1/16" rubber pads similar to those supplied with the new battery are adhered to the bottom (side closest to the PC Board) of the battery enclosure. If there are none, then adhere the four new 1/16" pads to the inside of the enclosure so that they will be under the center of each corner cell of the battery

pack when it is installed. If there are four, but they are 1/8" thick, remove and replace them with the 1/16" pads included with the battery. There should also be two 1/8" thick pads on the inside of the rear panel within the cutout in the battery enclosure gasket. If there are none, use the two included with the battery and adhere as shown.



4. Place the battery in the enclosure so that the label on the battery is facing the rear panel and fit the fuse holder into the space to the left of the battery.
5. Plug the connectors together outside the enclosure and set the grommet on the wire into the notch in the side of the enclosure so that the flat on the grommet will be facing the rear panel. If there is no flat edge ("D" shape) to the grommet, then cut one using side cutters. Be careful to leave the center hole in the grommet intact.
6. Replace the rear panel and four screws. Take care that the grommet remains in the notch when the panel is replaced.
7. Turn on the unit and check the battery charge status.
8. If the battery bar graph is indicating less than half capacity, charge for four (4) hours.

If valves are to be replaced, refer to DISASSEMBLY & REASSEMBLY INSTRUCTIONS.

E- PNEUMATIC CALIBRATION

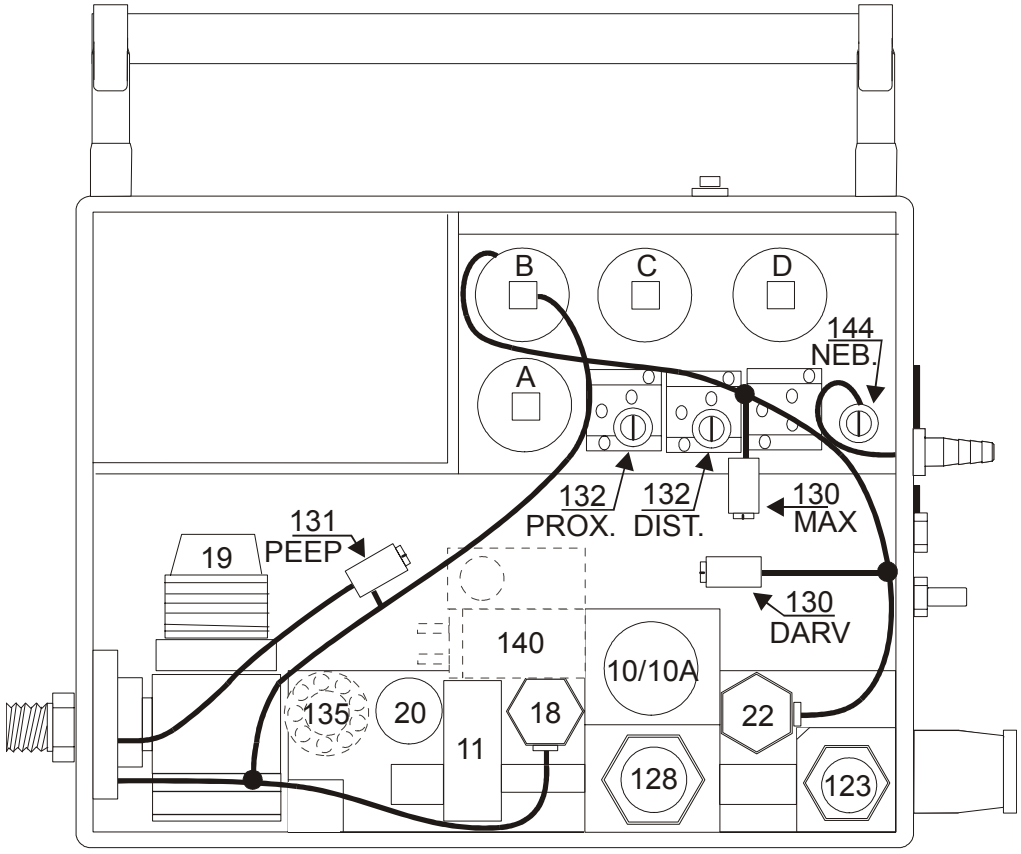


Fig.14 - CALIBRATION REFERENCE

19. Logic Regulator/Pilot Valve
20. Potentiometer
11. Flow Valve
135. Entrainment Flow Valve (Optional)
18. PEEP Valve
10. DARV (Diaphragm Actuated Relief Valve)
128. Positive Pressure Relief Valve
22. Maximum Pressure Valve
123. Vacuum Relief Valve
130. DARV Variable Resistor
144. Nebulizer Variable Resistor
130. Max Pressure Variable Resistor
132. Distal Flush Variable Resistor
132. Proximal Flush Variable Resistor
131. PEEP Variable Resistor
140. Entrainment Venturi (Optional)

These procedures are in two parts. The first part is "TO TEST". This describes the procedure used to test each specific component of the unit to determine its condition. The second part is "TO CALIBRATE". This part describes the calibration procedure of that component if it did not pass the preceding test. The calibration steps need only be performed on those components that fail the "TO TEST" procedure. Generally, calibration is only required when parts are serviced or replaced so be sure to troubleshoot any failed test thoroughly prior to resorting to calibration.

Caution: With the PC Board removed, great care should be taken to protect the board from stray voltages, static electricity, and any other environmental concerns that may damage the board. Always handle the board with care and be sure you and your work surface are properly grounded.

1. GAS SOURCE - 60% O2 / 100% O2

a. To ensure the most accurate calibration throughout all settings on the CV-4, a blended gas source of 60% O2 should be used.
b. 100% O2 should be used when entrainment is on, if installed.

2. SUPPLY PRESSURE - 44 - 66 PSI (303.6 – 455.4 kPa)

a. The pressure at the supply input on the CV-4 (not at the supply source) must be maintained between 44 - 66 PSI (303.6 – 455.4 kPa) at all times.

3. PEEP VALVE ZERO - ≤20 ML/M

NOTE: If the setscrews on the knob extender are not accessible from in front of the PCB, the PC Board will need to be removed if it's determined the valve stop must be adjusted in this step. See the caution at beginning of the calibration procedures.)

TO TEST:

a. Connect the exhalation valve port on the side of the CV-4 to a low flow test instrument.
b. Using hemostats or a similar tool, clamp off the blue PEEP line between the small cross fitting and the white bleed manifold mounted to the side of the case. Also clamp off the yellow line between the PEEP Variable Resistor (131) and the bleed manifold.
c. Turn the PEEP Valve (18) shaft fully CCW until a flow ≤20 ML/M is obtained as observed on the test instrument (Slight resistance in the valve at this point is normal, however, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

d. Remove the PC Board if the setscrews in the shaft extender are behind and not in front of the PC board. (See the caution at beginning of the calibration procedures.)
e. Clamp off the blue PEEP line between the small cross fitting and the white bleed manifold mounted to the side of the case. Also clamp off the yellow line between the PEEP Variable Resistor (131) and the bleed manifold.
f. Remove the shaft extender from the valve shaft by loosening the two setscrews. Turn the valve shaft until the specification stated above (3c) is met. Position the shaft extender on the PEEP Valve shaft with its stop pin against the left side of the stop. Tighten the setscrews in this position.

g. Remove hemostats.

4. MAXIMUM PRESSURE VALVE ZERO - ≤20 ML/M

NOTE: If the setscrews on the knob extender are not accessible from in front of the PCB, the PC Board will need to be removed if it's determined the valve stop must be adjusted in this step. See the caution at beginning of the calibration procedures.)

TO TEST:

a. Connect the exhalation valve port on the side of the CV-4 to a low flow test instrument.
b. Using hemostats or similar tool, clip off the yellow line between the Variable Resistor (130) and the DARV. **CAUTION**: Failure to do this could result in damage to the ventilator in the steps that follow.
c. Using hemostats or a similar tool, clamp off the orange line between the DARV Variable Resistor (130) and the white bleed manifold mounted to the side of the case. Also clamp off the orange line between the MAX Pressure Variable Resistor (130) and the bleed manifold.
d. In the test menu, activate valves, and turn on valve B.
e. Turn the MAX Valve (22) shaft fully CCW until a flow ≤20 ML/M is obtained as observed on the test instrument.(Slight resistance in the valve at this point is normal, however, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)
f. Remove the clamps from the orange bleed lines before removing the clamp from the yellow line to the DARV.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

g. Remove the PC Board if the setscrews in the shaft extender are behind and not in front of the PC board. (See the caution at beginning of the calibration procedures.)
h. Remove the DARV orange test plug from the cross next to the DARV Variable Resistor (130) and connect this barb to a low flow test instrument.
i. Clamp off the orange tube between the DARV Variable Resistor and the white bleed manifold as well as the orange tube between the MAX Pressure Variable Resistor and the bleed manifold.
j. Remove the shaft extender from the valve shaft by loosening the two setscrews.
k. Turn the valve shaft until the specification stated above (4d) is met. Position the shaft extender on the MAX Valve shaft with its stop pin against the left side of the stop. Tighten the setscrews in this position.
l. Remove hemostats.

5. FLOW VALVE/POTENTIOMETER ZERO - ≤500 ML/M

NOTE: The PC Board must be removed if it's determined the valve stop must be adjusted in this step. See the caution at beginning of the calibration procedures.)

NOTE: The Flow Valve (11) is geared to the Potentiometer (20) and it is the Potentiometer limits that stops the valve.

TO TEST:

a. Connect the Patient Connector on the side of the CV-4 to a low flow test instrument using a single length of tubing.
b. Occlude the opening of the DARV or turn up MAX Pressure fully if it's calibrated.
c. In the test menu, activate valves, and turn on valve A.
d. Turn the Flow Knob fully CCW to the stop. Flow should be ≤500 ML/M as

observed on the test instrument.

e. Entrainment Flow Valve (optional feature) - set up same as above (5a-c). Set the Entrainment Switch to ON. Occlude the entrainment opening in the venturi above the PEEP Valve.

f. Turn the Entrainment Flow Knob fully CCW to the stop. Flow should be ≤500 ml/M as observed on the test instrument.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

g. Remove the PC Board. (See the caution at beginning of the calibration procedures.)

h. Remove the gear from the Potentiometer by loosening the setscrews located in the teeth of the gear.

NOTE: Some units have only one setscrew in each hole, however, most will have two per hole, one on top of the other. Remove the top setscrew and then loosen the bottom one in both holes.

I. Carefully disconnect the clear tube from the PEEP Valve (18). Be sure the supply pressure is off at this point. Carefully remove the green tube connected to the Pilot Valve at the bottom of the Regulator and connect the clear tube here. This will turn on the patient flow whenever the supply pressure is turned on, thus bypassing the software and solenoid.

j. **Entrainment Flow Valve** (optional feature) - Carefully remove the clear tube from the front top row barb on the entrainment assembly. Connect this tube to a low flow test instrument.

k. Turn on entrainment, turn on the supply, and turn the Entrainment Flow Valve shaft CW until ≤500 ml/M is obtained. Leave the valve in this position.

NOTE: In the zero position, the valve gear should be flush with the end of the shaft and the setscrews should be on the bottom. If they are not, loosen them and reposition the gear so they are. Some units have only one setscrew in each hole, however, most will have two per hole, one on top of the other. Remove the top setscrew and then loosen the bottom one in both holes. To tighten, tighten the shorter one inside the hole first, then install and tighten the second setscrew. Do not over tighten the second one or the gear may distort causing it to bind.

l. Reconnect the clear tube to the entrainment barb.

m. **Flow Valve** - Connect the Patient Connector on the side of the CV-4 to a low flow test instrument using a single length of tubing.

n. Turn on the supply pressure, occlude the opening of the DARV or turn up MAX Pressure fully if it's calibrated, and turn the Flow Valve shaft CW until the flow measured is ≤500 ml/M. DO NOT FORCE. (Slight resistance in the valve at this point is normal. However, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)

NOTE: See note in 5k.

o. While leaving the Flow Valve in the zero position, turn the Potentiometer shaft fully CCW until it stops. Place the Potentiometer gear onto the shaft so it's setscrews are facing 180° opposite the screws on the flow shaft(s), i.e., at the top if the Flow Valve setscrews are at the bottom. This helps prevent binding as they mesh. This gear should only engage the flow gear(s) to half their thickness. This enables proper engagement throughout the full travel of the flow shaft(s) as it is turned and moves forward. Tighten the inner setscrews and replace and tighten the outer setscrews.

p. Test again and ensure that the Potentiometer hits it stop at the same time the Flow Valve reaches zero. Reconnect all tubing to its original state.

6. LOGIC REGULATOR - APPROX. 19/26 PSI (perform first - 5)

REMINDER: Supply should be 60% O2 (100% O2 with entrainment on, if installed) and input pressure at the Crossvent 44 – 66 PSI (303.6 – 455.4 kPa).

TO TEST:

a. Connect the Patient Connector on the side of the CV-4 to a high flow test instrument using a single length of tubing.
b. Occlude the opening of the DARV or turn up MAX Pressure if it's calibrated.
c. In the test menu, activate valves, and turn on valve A.
d. Turn the Flow Valve fully CW. The maximum flow should be within 108 - 132 LPM (102 - 138 LPM with entrainment on, if installed).
e. If this test fails, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Remove the locking o-ring (or wire) between the red locking ring and the Regulator Adjusting Knob and lift the ring towards the knob to unlock it.
g. Remove the orange test plug from the tee on the clear tube just off the regulator and connect a high pressure gauge here.
h. Connect the Patient Connector on the side of the CV-4 to a high flow test instrument using a single length of tubing.
i. Occlude the opening of the DARV or turn up MAX Pressure if it's calibrated.
j. In the test menu, activate valves, and turn on valve A.
k. Turn the Flow Valve fully CW. (Entrainment off, if installed).
l. Turn the Regulator Adjusting Knob until the specification stated above (6d) is met. The pressure as indicated on the gauge (6g) should be approximately 19 PSI (26 PSI if the CV-4 has the entrainment option installed). This pressure will vary slightly from unit to unit and is dependent upon the pressure required to obtain the maximum flow, therefore no specific pressure is given. However, if the pressure required is significantly higher or lower than these values, then there may a restriction or leak respectively.
m. Remove the test gauge and replace the test plug. Snap the locking ring back down in place and replace the o-ring (wire).

7. PEEP SIGNAL - 17 cmH2O (perform first - 3, 5, 6)

TO TEST:

a. Connect the exhalation valve port on the side of the CV-4 to a low pressure test instrument.
b. Fully open the PEEP Valve.
c. Pressure should be 15 - 20 cmH2O.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

d. Set up as in 7a-b.
e. Adjust the PEEP Variable Resistor (131) to obtain 7c.

8. MAXIMUM PRESSURE SIGNAL - 60 cmH2O (perform first - 4, 5, 6)

TO TEST:

a. Connect the exhalation valve port on the side of the CV-4 to a low pressure test instrument.

b. In the test menu, activate valves and turn on valves A and B.
c. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument).
d. Fully open the MAX Pressure Valve.
e. Pressure should be 54 - 66 cmH2O.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 8a - d.
g. Adjust the MAX Pressure Variable Resistor (130) to obtain 8e.

9. DARV SIGNAL - 65 cmH2O (perform first - 5, 6)

TO TEST:

a. Remove the orange test plug from the cross next to the DARV Variable Resistor (130). Connect this barb to a low pressure test instrument.
b. Fully open the Max Pressure Valve.
c. In the test menu, activate valves and turn on valve A.
d. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument)
e. Pressure should be 5 cmH2O above MAX Pressure as measured in step 8.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 9a - d.
g. Adjust DARV Variable Resistor to obtain 9e.

10. NEBULIZER FLOW - 7 LPM (perform first - 5, 6)

TO TEST:

a. Connect the nebulizer port on the side of the CV-4 to a high flow test instrument.
b. In the test menu, activate valves and turn on valves A and C.
c. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument).
d. Flow as measured from the nebulizer port should be 6.5 - 7.5 LPM.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Set up as in 10a - c.
f. Adjust the Nebulizer Variable Resistor (144) to obtain 10d.

11. FLUSH - 50 ML/M (perform first - 5, 6)

(Units with exhale tidal volume monitoring installed only)

TO TEST:

a. Connect the Patient Distal port on the side of the CV-4 to a low flow test instrument.
b. In the test menu, activate valves and turn on valves A and D.
c. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument).
d. Flow as measured from the distal port should be 40 - 60 ml/M.
e. Repeat for the Patient Proximal port.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 11a - c.
g. Adjust the Distal Variable Resistor (132) to obtain 11d.
h. Adjust the Proximal Flush Variable Resistor (132) to obtain 11d.

12. POSITIVE RELIEF VALVE - 96 - 144 cmH2O (perform first - 5, 6)

TO TEST:

a. Connect the Patient Connector on the side of the CV-4 to a low pressure test instrument using a single length of tubing.
b. Occlude the opening of the DARV.
c. In the test menu, activate valves, and turn on valve A.
d. Starting with the valve fully CCW, turn the Flow Knob fully CW while observing the test instrument. The pressure should be no less than 96 cmH2O with 20 LPM and no greater than 144 cmH2O with 120 LPM.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Set up the same as 12a - c.
f. Turn off valve A and remove the Positive Relief Valve (128).
g. From the underside of the valve, adjust the tension on the spring to obtain 12d by holding the spoked spring seat and turning the center poppet with a screwdriver. Turn CW if pressure is too high and CCW if too low.
h. Reinstall and test.

13. VACUUM RELIEF VALVE - - 4 cmH2O (perform first - 5, 6)

TO TEST:

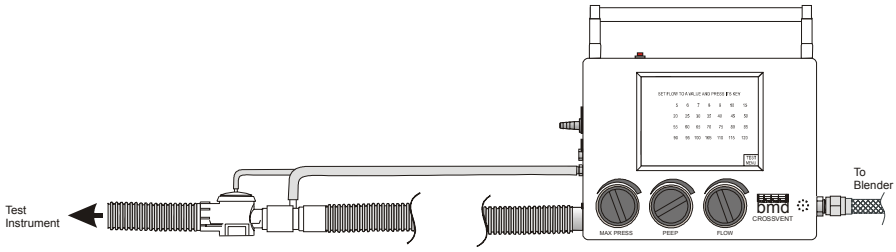
a. Connect the Patient Connector on the side of the CV-4 to a low flow test instrument using a single length of tubing. Into this tube, tee a low pressure vacuum test gauge.
b. Occlude the opening of the DARV.
c. Connect a controlled vacuum generating device to the output of the low flow test instrument so that air can be drawn through it.
d. Slowly increase the vacuum while observing the flow test instrument and the vacuum gauge. The Vacuum Relief Valve (123) should start to open between -3.5 and -4.5 cmH2O and the flow test instrument should indicate this by showing some flow at this point.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Set up the same as in 13a - c.
f. Remove the Vacuum Relief Valve (123). While holding the poppet from turning with your finger, adjust the tension on the spring by turning the spoked spring seat. Turn it CW to increase and CCW to decrease pressure.
g. Reinstall and test.

14. FLOW (entrainment off) (perform first - 5, 6, 7, 8, 9)

NOTE: For greatest accuracy, verify flow using a 60% O2 gas supply making certain that the pressure to the CV-4 inlet remains within specified pressure limits of 44-66 psi; (303.6 – 455.4 kPa) *at all flows. This may require a supply pressure to the blender to be 70 PSI or greater when checking the higher flows.*



TO TEST:

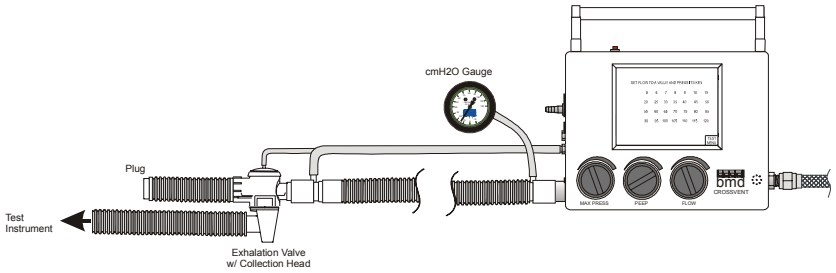
a. Connect a patient circuit to the Crossvent as illustrated.
b. Increase the supply pressure to the blender to 75 psi.
c. Turn Max Pressure and PEEP on fully, making certain that the proximal airway pressure line is connected.
d. Connect the patient hose to an external test instrument capable of measuring flow.
e. After turning ON the CV-4, press the TEST Button and then VALVES.
f. Turn on Valve A.
g. Adjust the flow knob and observe the flow as indicated on the test instrument. It should be within 10% of the displayed flow on the Crossvent where it indicates "FLOW".
h. If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

i. Press "FLOW" in the TEST menu and enter the authorization code.
j. Adjust the flow knob until the actual measured flow, as indicated on the test instrument, is equal to 5 lpm. Then compare this actual measured flow to the flow value indicated in the lower portion of the Crossvent display. If the flow as indicated by the Crossvent is within ±10% of the actual flow, in this case 4.5 – 5.5 lpm, proceed with the next flow point in the table. If it is not within the 10% limits, press the "5" key in the table corresponding to the actual flow. The displayed flow on the Crossvent should now display 5 lpm. The flow knob is now calibrated to the actual flow for that setting. Repeat for all other flow points.

15. FLOW (entrainment on) **(perform first - 5, 6, 7, 8, 9)**

NOTE: For greatest accuracy, verify flow using a 100% O2 gas supply making certain that the pressure to the CV-4 inlet remains within specified pressure limits of 44-66 psi (303.6 – 455.4 kPa) *at all flows.*



TO TEST:

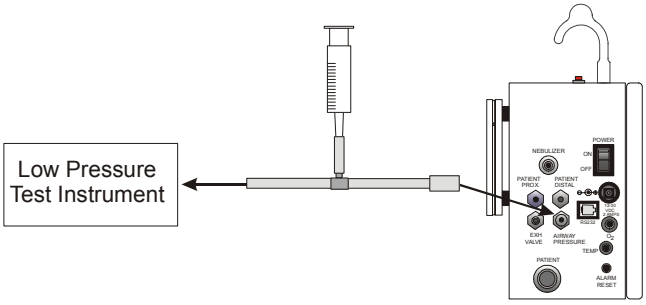
a. Connect a patient circuit to the Crossvent as illustrated.
b. Turn on entrainment using the knob on the side of the ventilator.
c. Turn Max Pressure on fully, making certain that the proximal airway pressure line is connected.
d. Connect the patient hose from the exhaust of the exhalation valve to an external flow-measuring device.
e. After turning ON the CV-4, press the TEST Button and then FLOW to access the Flow Test Menu. Enter the authorization code.

f. Adjust the PEEP Knob until 15 cmH_2O is observed in the analog gauge. All flow readings should be taken with this backpressure. Readjust as necessary as each flow value is set. At the higher flows, this pressure may go above 15 cmH_2O and you may not be able to adjust it down. This is acceptable.
g. Adjust the flow knob and observe the flow as indicated on the test instrument. It should be within 10% of the displayed flow on the Crossvent where it indicates "FLOW". If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

h. Setup same as above.
i. Adjust the flow knob until the actual measured flow, as indicated on the test instrument, is equal to 5 lpm. Then compare this actual measured flow to the flow value indicated in the lower portion of the Crossvent display. If the flow as indicated by the Crossvent is within ±10% of the actual flow, in this case 4.5 – 5.5 lpm, proceed with the next flow point in the table. If it is not within the 10% limits, press the "5" key in the table corresponding to the actual flow. The displayed flow on the Crossvent should now display 5 lpm. The flow knob is now calibrated to the actual flow for that setting. Repeat for all other flow points while holding a PEEP of 15 cmH_2O as described previously.

16. PRESSURE CALIBRATION



TO TEST:

a. Tee a 10-25 ml syringe into a tube that connects the airway pressure fitting on the Crossvent to a low pressure test device.
b. Turn on the Crossvent.
c. While pushing in and varying the plunger on the syringe, observe the pressure bar graph and PEAK reading above the graph.
d. The readings on the display should be within 3% of the readings on the test instrument. If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Turn the unit on and press the CAL key.
f. Press the PRESSURE key.
g. With the airway pressure connector on the side of the unit open to atmosphere (zero pressure), press the key marked zero.
h. Set up as in "a".
i. Apply 100 cmH_2O pressure to the airway pressure connector and press the 100 cmH_2O key.

F- TECHNICAL TROUBLESHOOTING CHART

NOTE: A performance test should always be completed before proceeding with repairs.
CAUTION*:* Always follow proper static grounding procedures when removing or replacing electronic parts, LCD ass'y, etc.

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Auto cycling of the ventilator.	Pressure out of calibration. Sensitivity set too low.	Re-cal pressure. Increase Sensitivity setting.
Battery low audible and visual alarm.	Low battery.	Charge battery.
Battery will not charge. External power ok.	Battery fuse open. Battery open. Battery cable open	Replace F2. Replace battery. Repair cable.
No battery operation.	Battery fuse open. Battery not charged. Q3 & R7 open.	Replace F2. Charge battery. Replace Q3 or R7.
External power failure alarm - BATT flashing.	Loss of external power. AC adaptor defective.	Check input mains. Replace ac adaptor.
Ventilator will not power up from ext power. Battery operation ok.	Fuse F1 open. AC adaptor defective. VR1 or Q1 open.	Replace F1. Replace AC adaptor. Replace VR1 or Q1.
Ventilator fails key test. All other functions normal.	Defective keypad. Bad IC11 or IC12. Poor Connection at J6,J7	Replace keypad. Replace IC11 or IC12. Reconnect J6, J7 or return to factory.
Ventilator fails RAM test.	Defective IC4.	Replace IC4 and re-cal or return to factory.
Ventilator fails ROM test.	Defective IC3.	Reprogram IC3 Replace IC3 or return to factory.
Ventilator fails display test.	Defective LCD. Defective IC9. Improper voltages.	Replace LCD. Replace IC9. Return to factory.
Oxygen will not calibrate.	Aged sensor. Bad IC16 or VR5. Bad cable.	Replace sensor. Replace IC16. Replace VR5. Replace sensor. Return to factory.

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Pressure will not calibrate.	Tubing leak. PS4 bad.	Replace tubing. Replace PS4.
Pressure unable to reach 120cmH2O during operation.	Loosing pressure through Pressure Relief Valve. DARV leaking at seat or signal pressure too low.	Clean, re-cal or replace Relief Valve. Clean seat, repair leak, re-cal or replace.
Flow will not cal. (see following symptom also)	Defective flow encoder. Bad IC15. Defective atmospheric compensation circuit.	Replace 10k pot. Replace IC15. Check PS1 and assoc. circuits.
Flow will not reach 120 LPM or displayed flow does not agree with actual flow.	Supply pressure too low. Max Pressure not on or defective. Flow restriction or leak. Input filter clogged. Regulator set too low. Flow valve defective.	Check supply pressure at ventilator input fitting while gas is flowing. Should meet specification on side of case. Set Max Pressure fully on or repair. Check for restrictions and leaks in flow path. Replace filter and resolve cause. Calibrate regulator pressure. Check flow valve.
Pneumotach reading greatly inaccurate.	Pneumotach installed backwards. Tubing leak. PS3 defective.	Check installation. Check tubing. Replace PS3 and/or check associated circuits.
Fail to cycle alarms. (see Appendix E)	Open solenoid A or B Shorted solenoid A or B Bad solenoid wire assy. Bad IC8. Communication error	Replace solenoid. Replace solenoid wire. Replace IC8. Power off/on, if persists then return to factory
CV-4 totally inoperative.	Bad battery and no external power. Major internal problem	Check appropriate symptoms above. Return to factory

G- DISASSEMBLY & REASSEMBLY INSTRUCTIONS

Note: Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

1. BATTERY REMOVAL/REPLACEMENT

Refer to Preventative Maintenance in this section.

2. ACCESS TO PNEUMATICS

a. Remove the four (4) screws from the rear panel.
b. Remove the rear panel from the CV-4.

3. AIRFLOW PNEUMATICS

a. RELIEF VALVES, FLOW & PEEP VALVES, FLOW POTENTIOMETER & DRV.
   I. For ease of parts replacement, the complete main Pneumatic ass'y should be removed.
   II. Remove complete PCB ass'y - see below.
   III. Remove both of the clear hose clamps.
   IV. Remove clear hose.
   V. Remove the three (3) 6-32 pan head screws on bottom of chassis case.
   VI. Carefully slide out the angle bracket ass'y holding the main pneumatics.
   VII. Replace appropriate defective ass'y and/or replace the complete pneumatic assy.
   VIII. Re-assemble in the reverse sequence.

b. PRESSURE REGULATOR
   I. Remove the two (2) 4-40 pan head screws holding the bleed exhaust manifold.
   II. Remove both of the clear hose clamps (tie wraps).
   III. Remove hose.
   VI. Using 2 - 3/4 inch open-end wrenches, remove supply inlet fitting.
   V. Remove and replace regulator.
   VI. Observe proper tubing color and its termination.
   VII. Re-assemble in the reverse sequence.

c. SOLENOID/GATE BRACKET ASSY OR INDIVIDUAL PART REPLACEMENT
   I. Remove complete PCB ass'y - see below
   II. Identify defective part (SOL A, B,C or D - GATE 1,2 or 3.
   III. Remove appropriate screw holding defective part.
   VI. Carefully remove tubing.
   V. Replace defective part.
   VI. Re-install appropriate tubing or replace if too short.
   VII. Re-assemble in the reverse sequence.

TO REPLACE COMPLETE SOLENOID/GATE BRACKET ASSY

VIII. Remove nebulizer fitting.
IX. Loosen the three (3) 6-32 x 1/4 nuts holding the solenoid bracket.
X. Remove the four twisted wire pairs to solenoids.
XI. Disconnect the small blue & clear tubing going to PS3 on the PCB.
XII. Disconnect appropriate tubing to ass'y from the main case.
XIII. Carefully jockey the ass'y out of the case.
XIV. Re-assemble in the reverse sequence.

NOTE: For ease of installation, replace the four twisted wire pairs prior to installing the new ass'y into the case.

4. ACCESS TO ELECTRONICS

WARNING: ANTISTATIC PROCEDURES MUST BE FOLLOWED.

a. Remove the four (4) screws from the rear panel.
b. Remove the knobs and front panel by carefully pulling up on one side of the panel. Be careful of the RF gasket around the edge of the front panel.

5. TOUCH SCREEN REPLACEMENT

a. Remove the two ribbon cables (J6 & J7) to PCB.
b. Using a hex allen wrench, carefully remove the four (4) 4-40x5/8 button head screws from the touch screen.
c. Carefully remove the touch screen making sure the four metal spacers remain in their appropriate position.
d. Replace new touch screen and secure in reverse sequence.
e. Make sure that the braided ground wire is attached to the upper right corner screw of the touch screen.

6. LCD PANEL REPLACEMENT

a. Remove touch screen (5a- 5c)
b. Remove cable to J4 on PCB (backlight).
c. Remove the four metal spacers.
d. Lift the LCD ass'y and then disconnect ribbon cable from J5.
e. To replace with a new LCD, carefully insert ribbon cable into J5.

CAUTION: THIS IS A VERY FRAGILE RIBBON ASSY.

f. Lay the LCD in position and place in position the four metal spacers.
g. Lay the touch screen in place and install the four 4-40x5/8 screws
NOTE: make sure the four metal spacers are captive.
h. Install the backlight wire ass'y to J4
I. Install the two ribbon cables from the touch screen to J6 & J7.
j. Make sure that the braided ground wire is attached to the upper right corner screw of the touch screen.

7. ACCESS TO MAIN PCB

a. Remove touch screen and LCD panel as in 5 & 6.

8. COMPLETE PCB REMOVAL

a. Disconnect the blue, clear and large clear tubing to the pressure transducers PS3 & PS4. Access these from the pneumatics side.
b. Remove the four (4) 6-32x1/4 button head allen screws in the four corners of the PCB.
c. Remove the four twisted pair cable from J11 thru J14.
d. Remove the led wire from J17.
e. Disconnect the battery by separating the battery connector.
f. Loosen the heat-sink ass'y nuts so that it is free to slide out with the PCB.

CAUTION: BE CAREFUL NOT TO LOOSE THE MYLAR INSULATOR UNDER THE HEATSINK ASSY.

NOTE: When removing the PCB, take care as to not loose the black reset cap on switch SW2.

g. Facing the CV-4, carefully tilt the right side up and gently slide the PCB out from the gasket area on the left. The heat-sink ass'y may have to be gently maneuvered to clear the battery compartment and LED.
h. To reinstall PCB, reverse sequence.

X. PARTS LIST AND SCHEMATIC DIAGRAMS

A- REPLACEMENT PARTS LIST

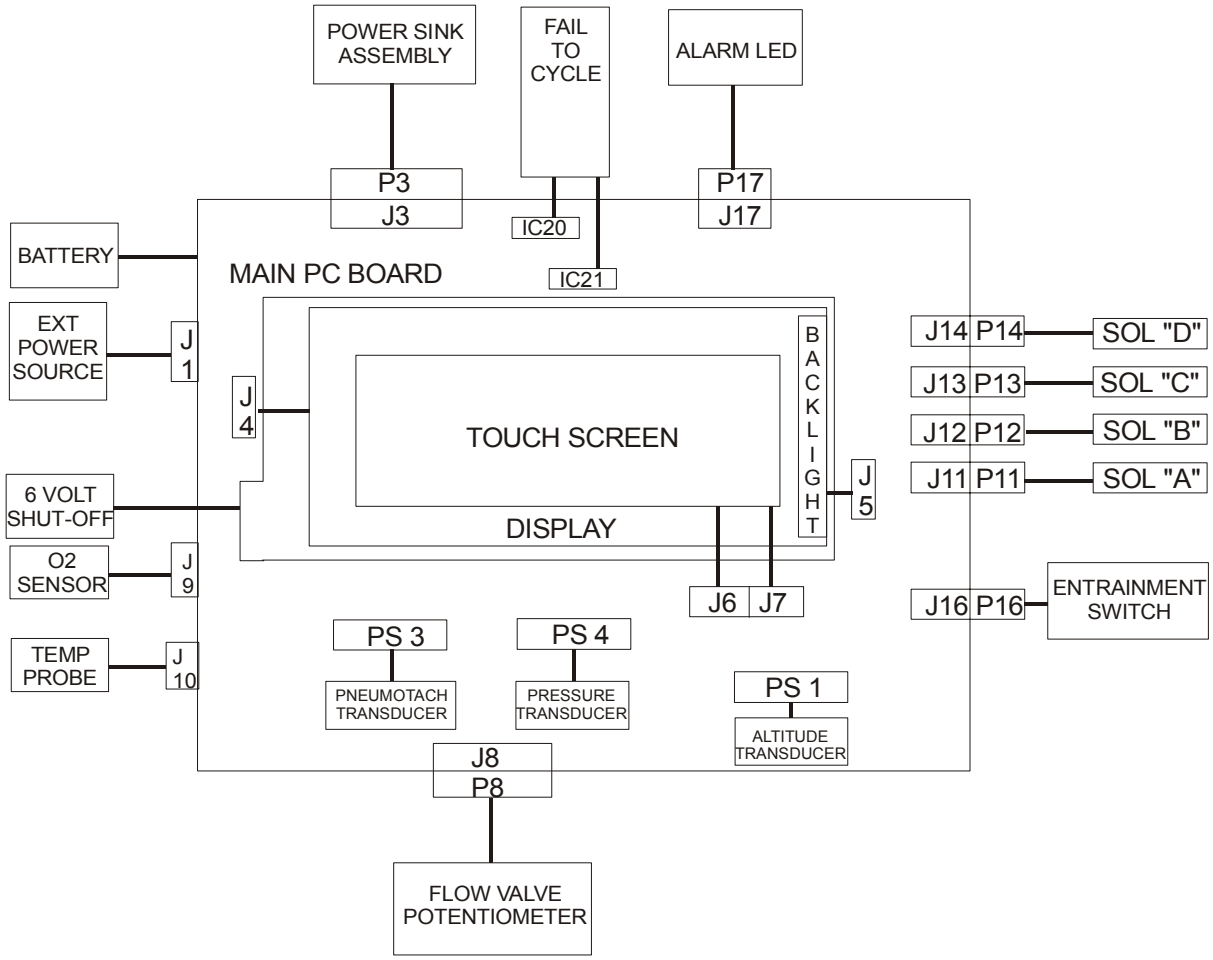
NOTE: SERIAL NUMBER OF VENTILATOR MUST ACCOMPANY ALL PARTS ORDERS

ITEM	PART #	DESCRIPTION
1	PRT4448	KIT, PREVENTIVE MAINTENANCE (UNITS W/ EXHTV MONITOR)
2	PRT4449	KIT, PREVENTIVE MAINTENANCE (UNITS W/O EXHTV MONITOR)
3	PRT4450	KIT, PREVENTIVE MAINTENANCE (UNITS W/ ENTRAINMENT & EXHTV MONITOR)
4	PRT4451	KIT, PREVENTIVE MAINTENANCE (UNITS W/ ENTRAINMENT BUT W/O EXHTV MONITOR)
6	PRT4402	ASSY, BATTERY 7.2V 6 D-CELL NICAD 5AH (Do not substitute)
11	PRT4407	ASSY, FLOW VALVE
13	PRT4409	ASSY, LCD DISPLAY
14	PRT4410	LED, ALARM
16	PRT4412	ASSY, PC BOARD COMPLETE WITH ALL IC'S
17	PRT4413	ASSY, PC BOARD, COMPLETE W DISPLAY & TOUCH SCREEN
18	PRT4414	ASSY, PEEP VALVE
19	PRT4415	ASSY, PILOT VALVE
22	PRT4414	ASSY, PRESSURE VALVE
23	PRT4419	ASSY, SOLENOID VALVE "A"
24	PRT4420	ASSY, SOLENOID VALVE "B"
25	PRT4421	ASSY, SOLENOID VALVE "C"
26	PRT4422	ASSY, SOLENOID VALVE "D"
33	4416A	CHARGER w/US HOSPITAL GRADE CORD (Do not substitute)
34	4416B	CHARGER w/EURO UNTERMINATED CORD (Do not substitute)
36	PFIL008	FILTER, DUCK BILL
80	EOVE004	KEYPAD MATRIX 8 x 8
128	PVAL029	VALVE, PRESSURE RELIEF
130	PRT4425	MAX/DARV PRESSURE LINE

X. PARTS LIST AND SCHEMATIC DIAGRAMS- cont.

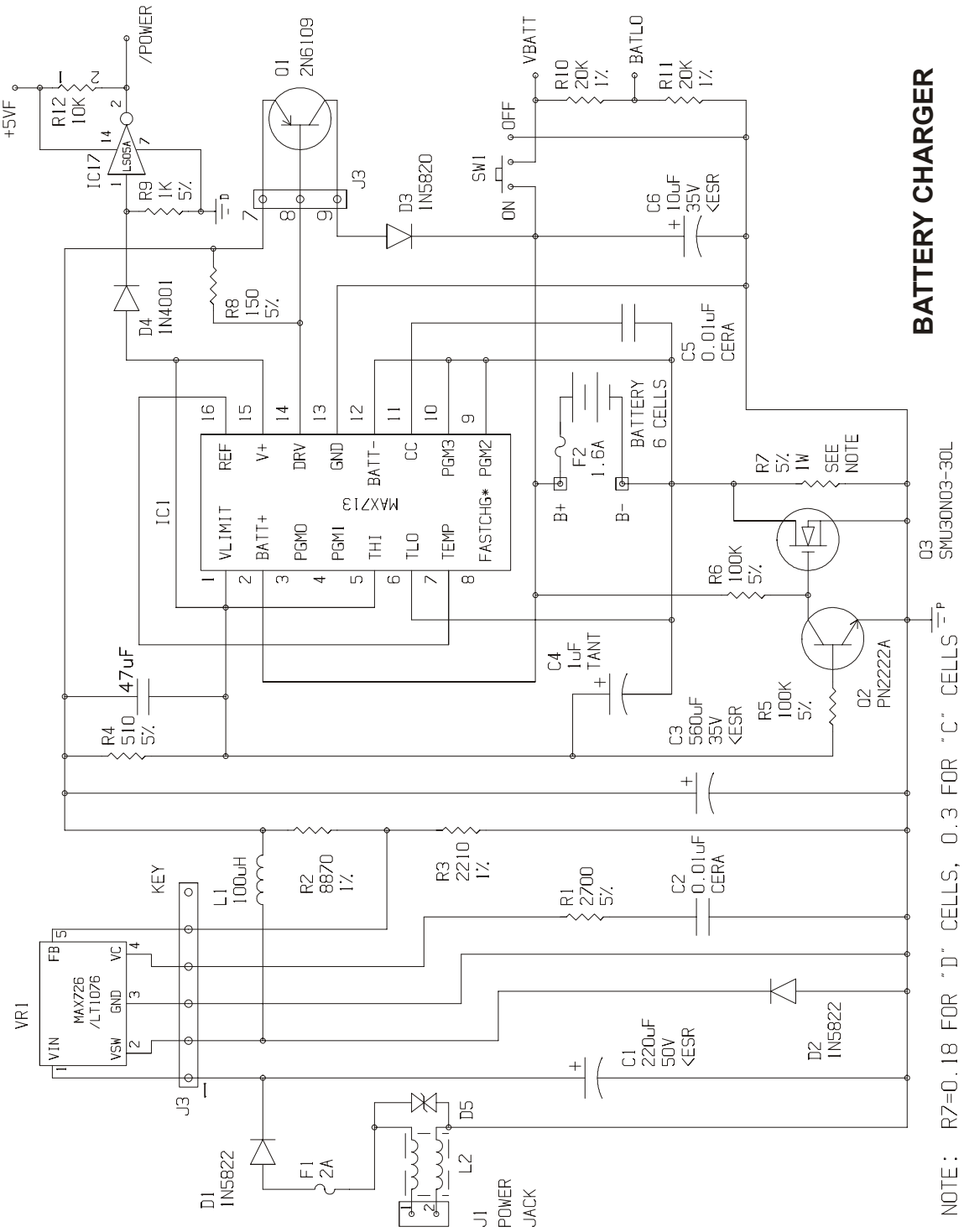
NOTE: SERIAL NUMBER OF VENTILATOR MUST ACCOMPANY ALL PARTS ORDERS.

ITEM	PART #	DESCRIPTION
131	PRT4426	PEEP PRESSURE LINE
132	PRT4428	FLUSH LINE
144	PRT4445	ASSY, NEBULIZER LINE
154	PRT4455	BACKLIGHT



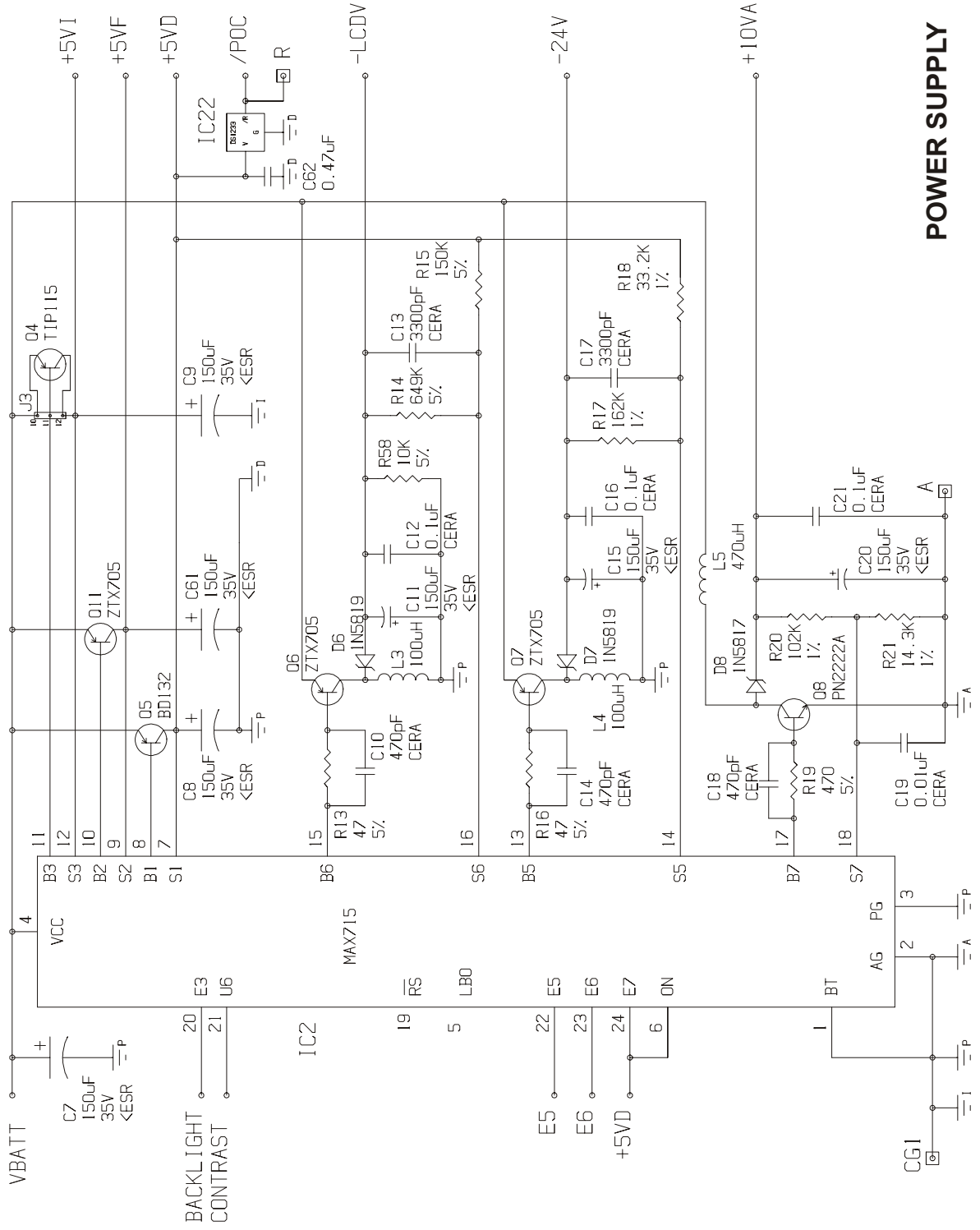
CV-4 ELECTRICAL BLOCK DIAGRAM

B- SCHEMATICS



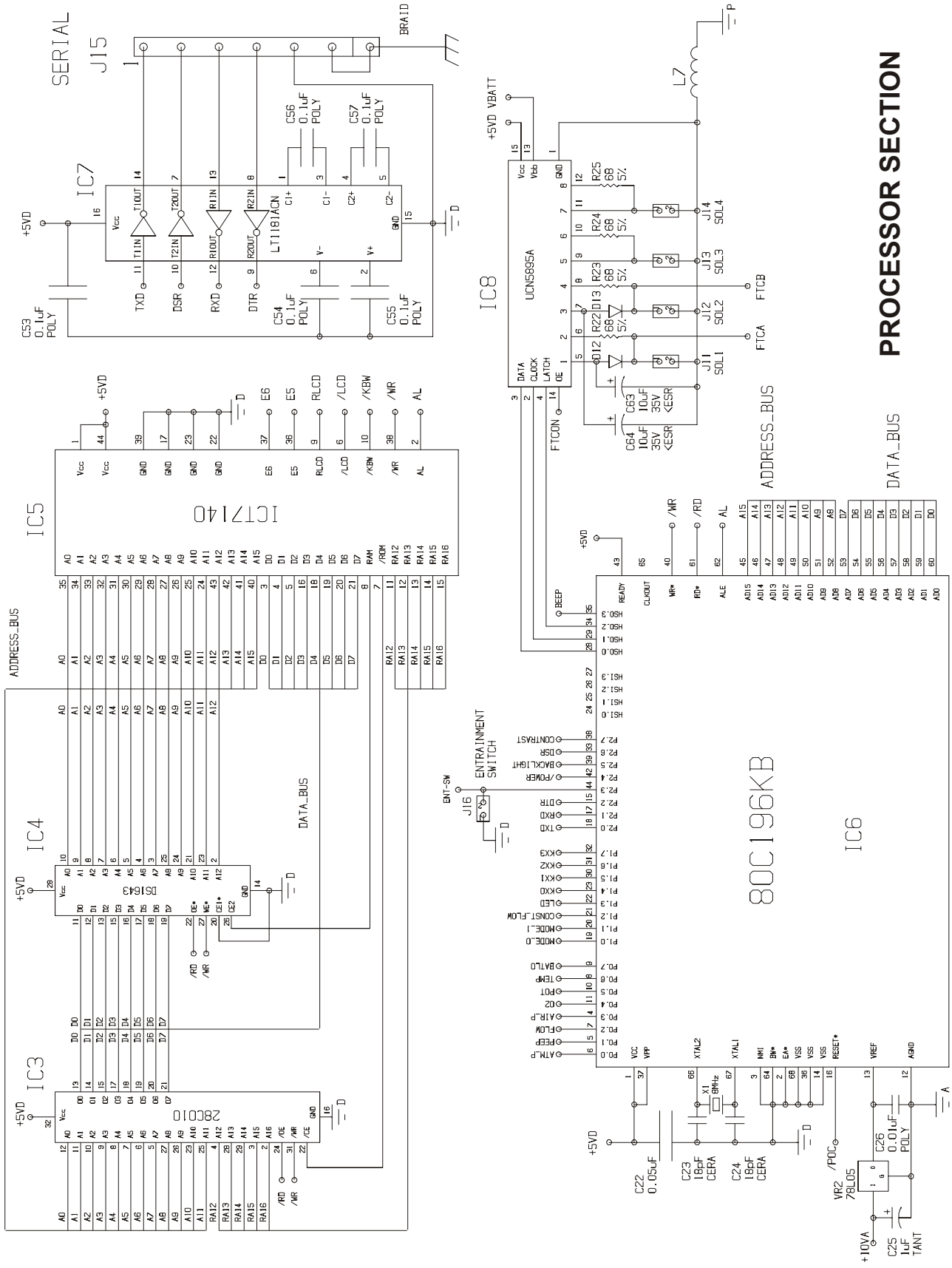
X. PARTS LIST AND SCHEMATIC DIAGRAMS- cont.

CIRCUIT SCHEMATICS



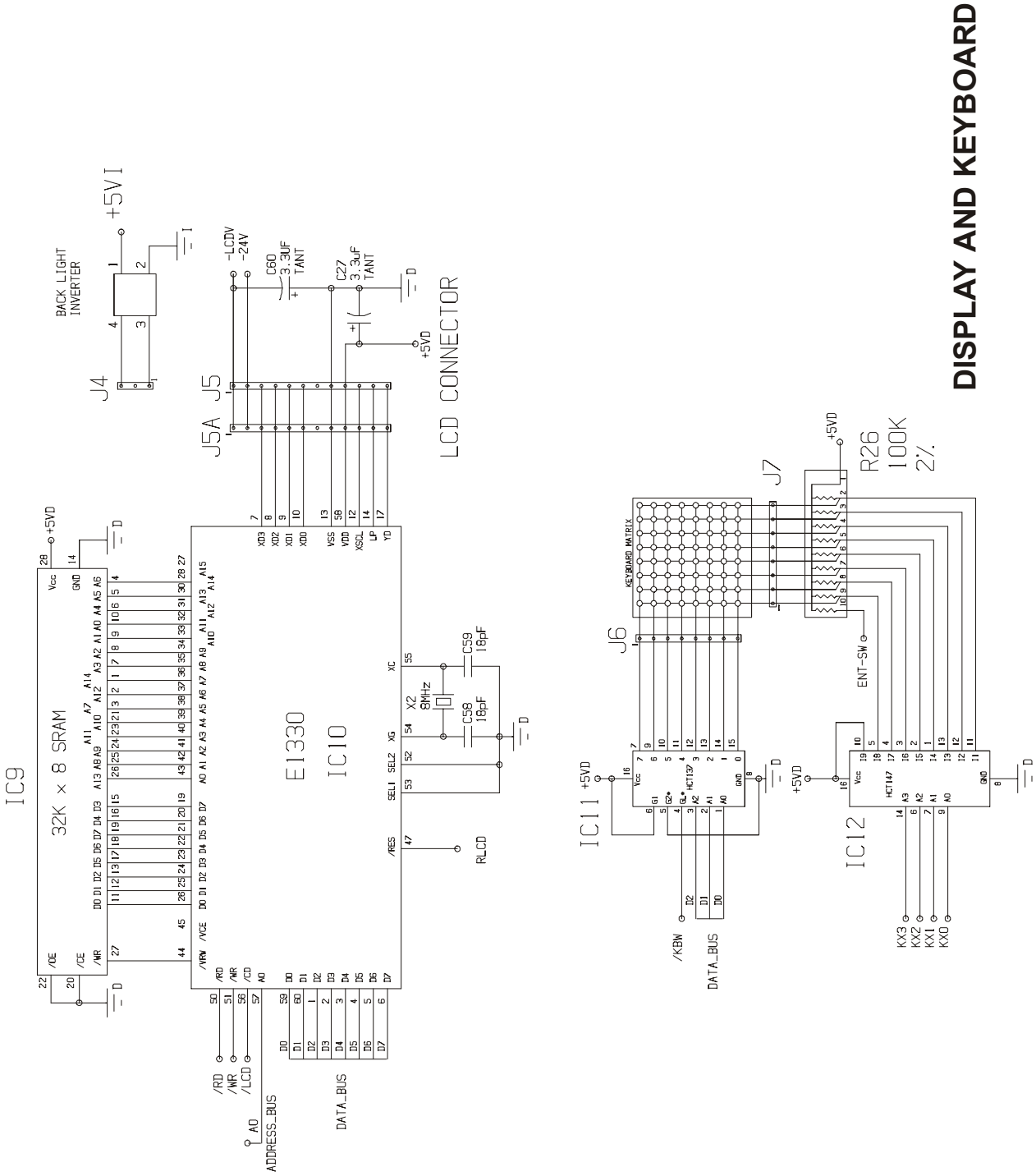
X. PARTS LIST AND SCHEMATIC DIAGRAMS- cont.

CIRCUIT SCHEMATICS

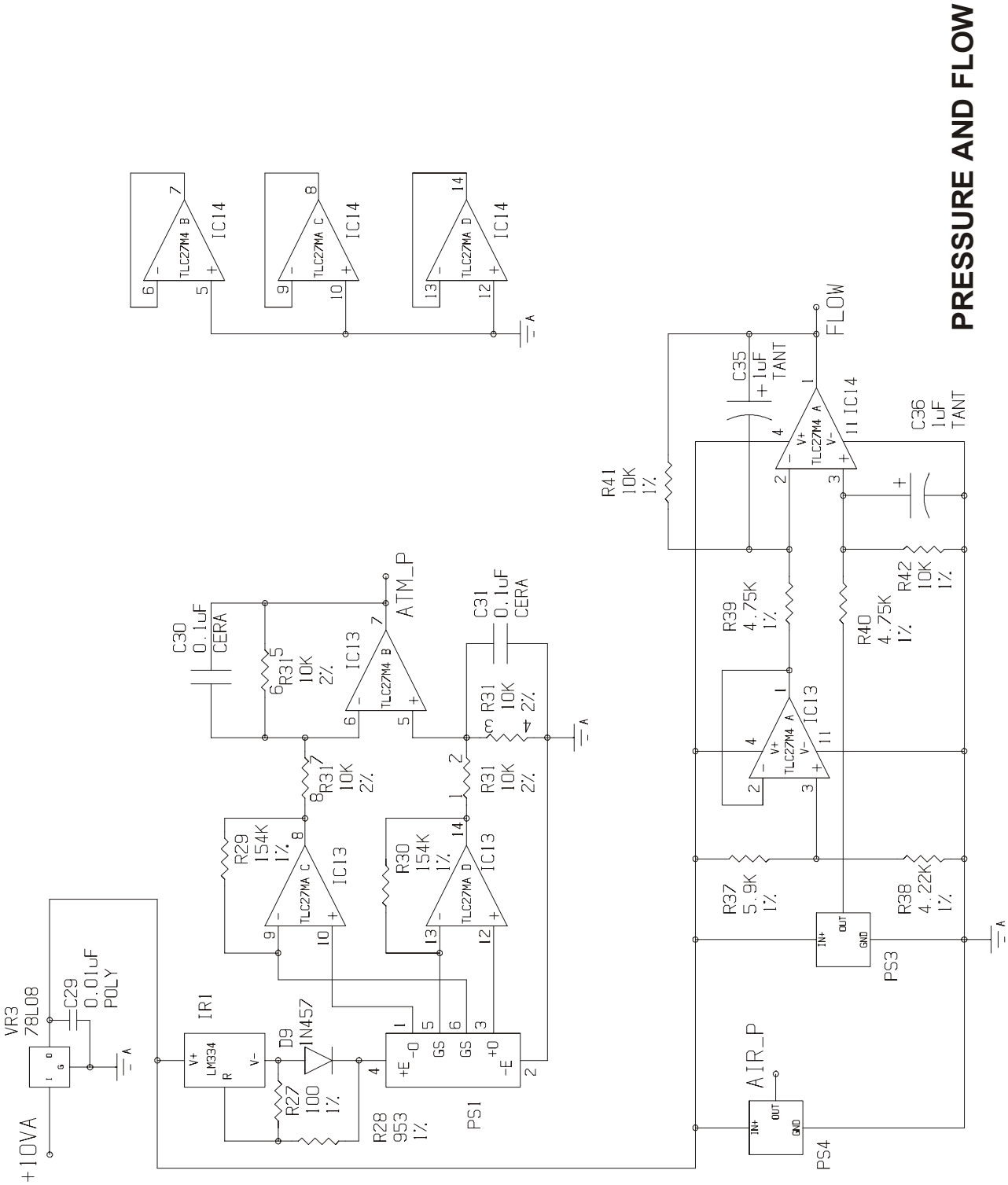


X. PARTS LIST AND SCHEMATIC DIAGRAMS- cont.

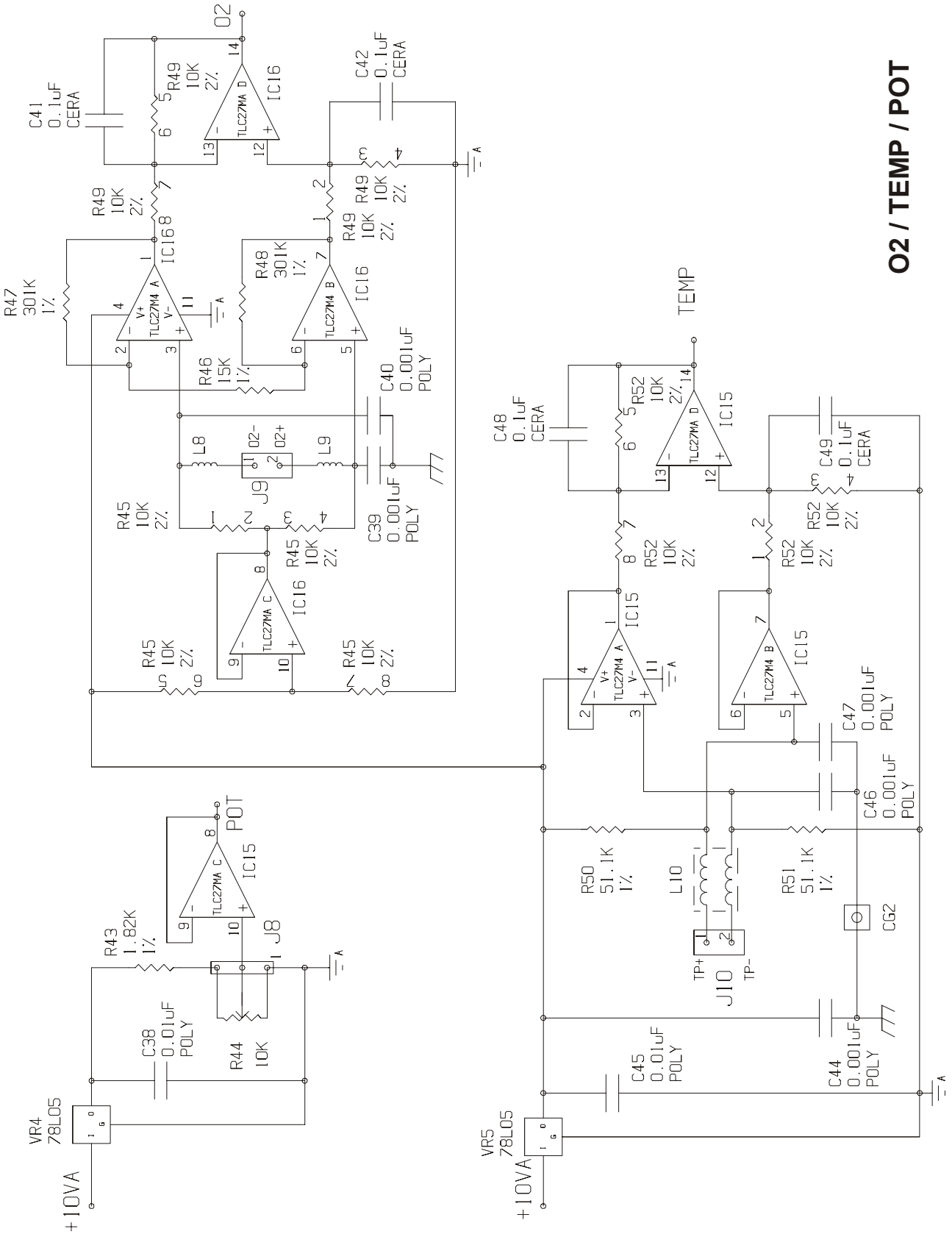
CIRCUIT SCHEMATICS



CIRCUIT SCHEMATICS

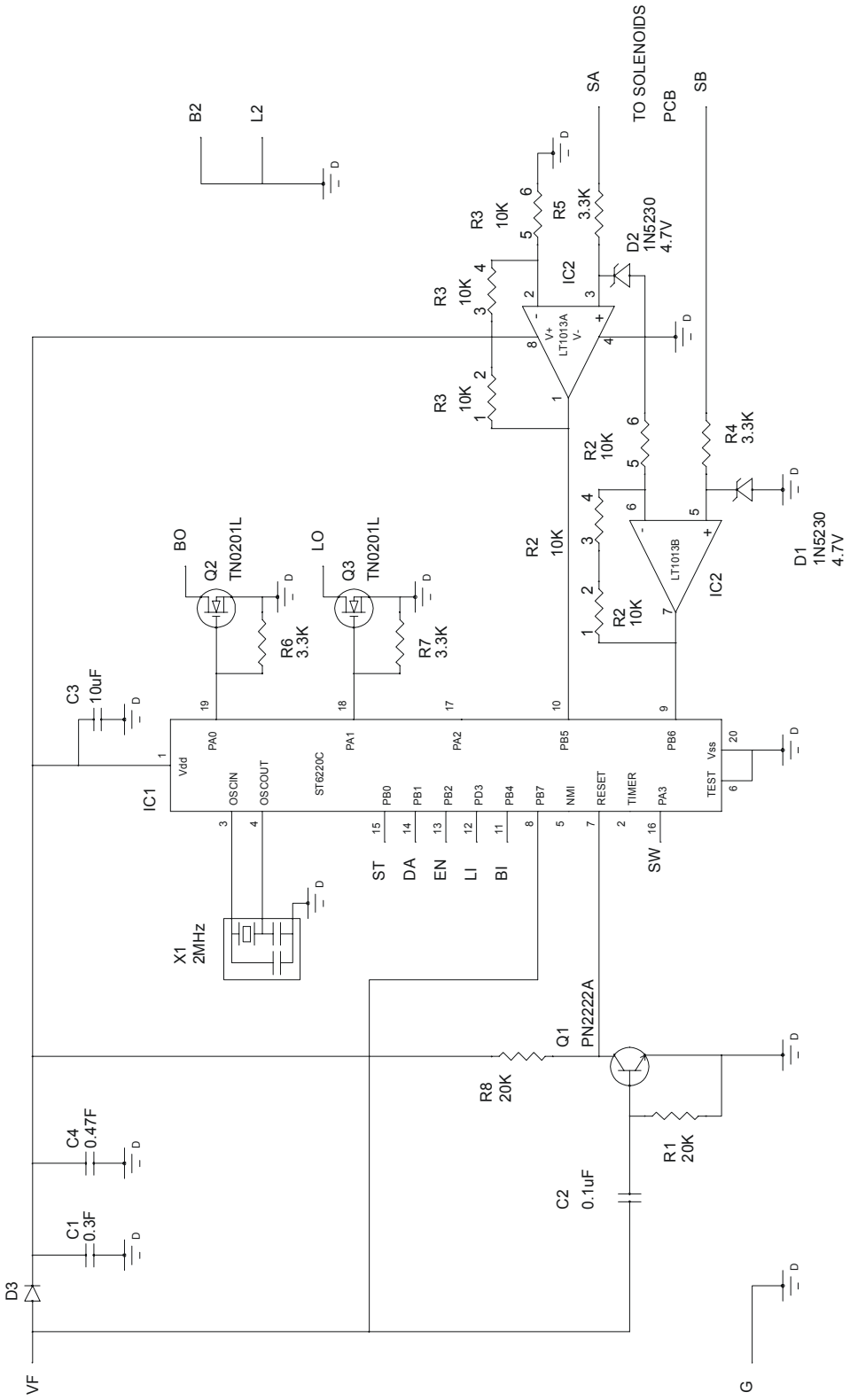


CIRCUIT SCHEMATICS



X. PARTS LIST AND SCHEMATIC DIAGRAMS- cont.

CIRCUIT SCHEMATICS



POWER AND FTC ALARM

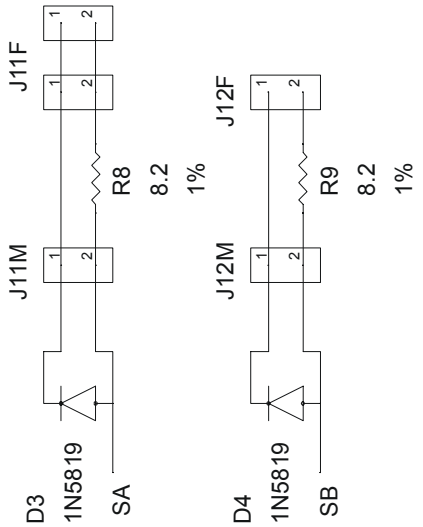
THIS CIRCUIT PLUGS INTO THE CROSSVENT PCB VERSION 7 OR VERSION 8.

IT REPLACES THE FOLLOWING COMPONENTS:

IC18, IC19, IC20, IC21, R53, R54, R56, R57, C50, C51, Q9 AND Q10.

EITHER C1 OR C4 IS USED, BUT NOT BOTH.

CIRCUIT SCHEMATICS



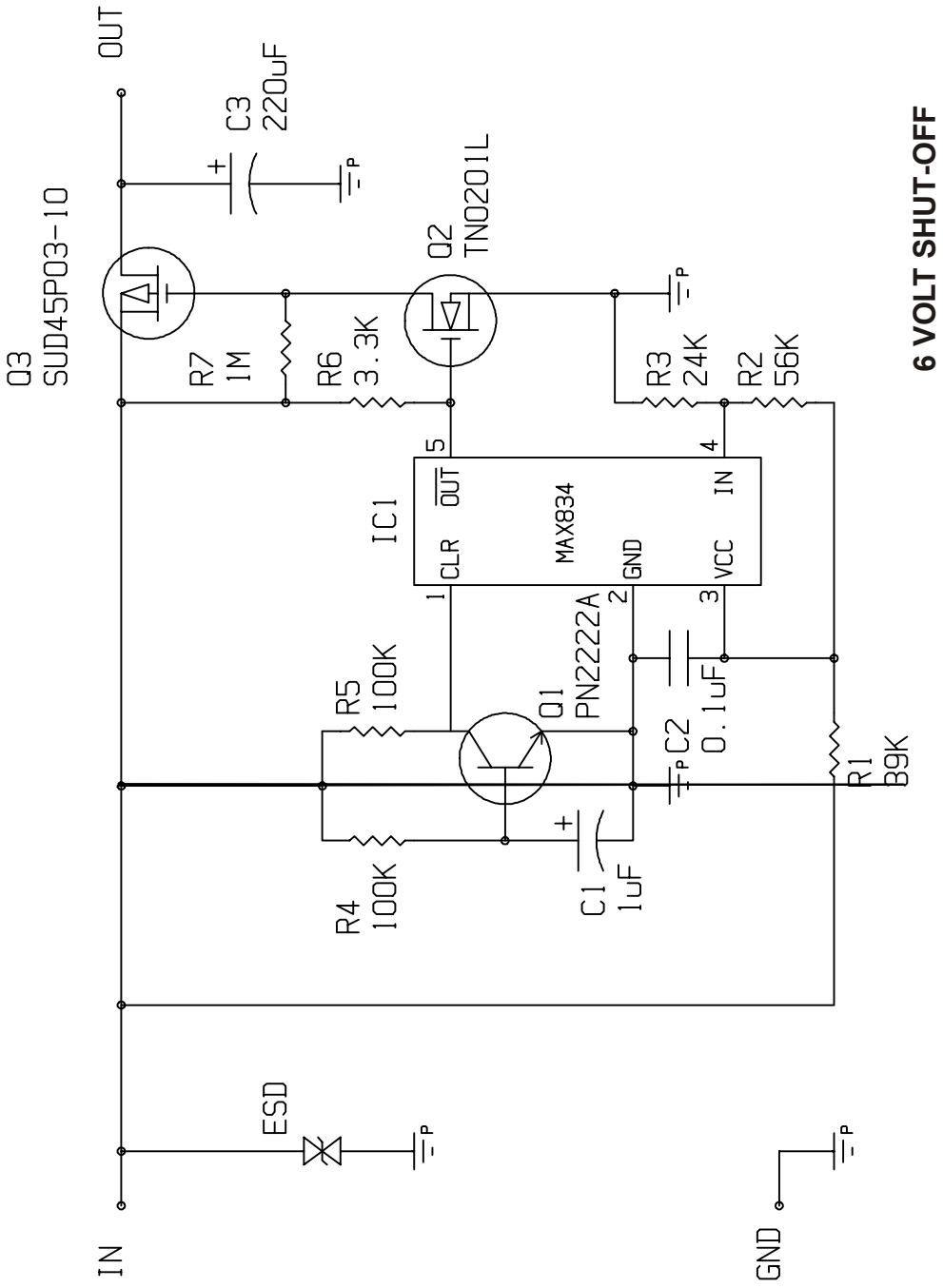
THIS CIRCUIT IS BUILT ON A PCB THAT IS ADDED TO THE CROSSVENT PCB VERSION 7 OR VERSION 8. IT CONNECTS TO THE MAIN ALARM BOARD.

J11F AND J12F ARE FEMALE HEADERS THAT MATE WITH J11 AND J12 ON THE MAIN PCB.

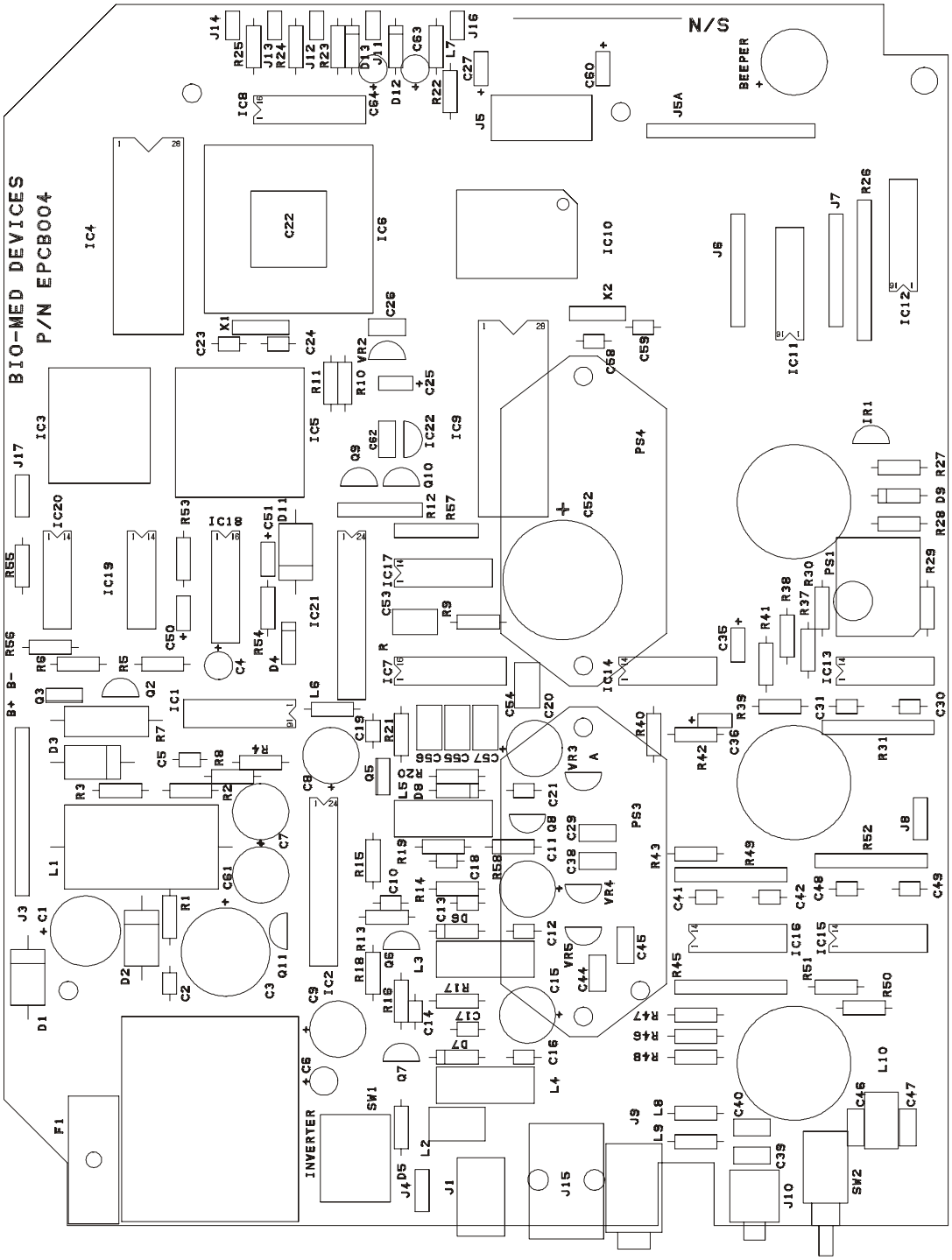
J11M AND J12M ARE MALE (PIN) HEADERS THAT THE SOLENOID CABLES PLUG INTO.

SOLENOID HEADER

CIRCUIT SCHEMATICS



COMPONENT LOCATIONS



WARRANTY

BIO-MED DEVICES, INC. expressly warrants to the PURCHASER, this Ventilator to be free from defects in material and workmanship for a period, from the date of purchase of one (1) year. BIO-MED DEVICES, INC. will repair or, at its option, replace any part or all of this ventilator which fails to conform to this warranty at no cost to the PURCHASER for materials and labor. The warranty does not apply to the patient circuit and hoses supplied with the instrument nor does the warranty cover abuse or misuse of the instrument, or damage due to unauthorized servicing.

BIO-MED DEVICES, INC. will pay any shipping charges required in repairing or replacing any part or all of this ventilator within three (3) months from the date of purchase. Thereafter, shipping charges will be paid by the PURCHASER.

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED.

This warranty shall become null and void if the Ventilator is opened, otherwise tampered with or if repairs are attempted by the PURCHASER, or if the Ventilator is operated by anyone other than trained and duly qualified medical personnel, or if the “Warranty Registration Card” is not returned within four (4) weeks of the date of purchase to:

BIO-MED DEVICES, INC.
61 Soundview Road
Guilford, CT 06437 USA
203-458-0202

APPENDIX A

ABBREVIATIONS

BPM	-	Breaths Per Minute
BPH	-	Breaths Per Hour
LPM	-	Liters Per Minute
ms	-	Milliseconds
ml	-	Milliliters
C	-	Degrees Centigrade
F	-	Degrees Fahrenheit
cmH_2O	-	Centimeters of Water Pressure
ml/cmH_2O	-	Milliliters Per Centimeter Water
L	-	Liters
VAC	-	Volts of Alternating Current
VDC	-	Volts of Direct Current
HZ	-	Hertz (Cycles Per Second)
LED	-	Light Emitting Diode
LCD	-	Liquid Crystal Display
psi	-	Pounds Per Square Inch
kPa	-	Kilopascals
Kg/cm^2	-	Kilograms Per Centimeter Square
PEEP	-	Positive End Expiratory Pressure
CPAP	-	Continuous Positive Airway Pressure
SIMV	-	Synchronized Intermittent Mandatory Ventilation
DISS	-	Diameter Index Safety System
I/E	-	Inspiratory To Expiratory Ratio
Asist Cntrl	-	Assist Control
TV	-	Tidal Volume
INSP	-	Inspiratory
EXP	-	Expiratory
EXH	-	Exhalation
PROX.	-	Proximal
TEMP	-	Temperature
dB	-	Decibels

APPENDIX B

DEFAULT SETTINGS

These are the settings that will be made by the software if all power to memory is lost or if a complete test routine is performed.

Mode: Assist Control
Modality: Auto shift
Rate: 12bpm
Tidal Volume: 500ml
Sensitivity: 1 cmH_2O
SIMV rate: 4 bpm
Sigh: off
Pressure support: off
Plateau: off
Constant flow: Off
Shift delay: 20 sec.
Nebulizer: Off
Nebulizer time: 1 second
Alarm limits set to minimum low and maximum high limits
Alarms with an Off function are set to Off
Language: English

APPENDIX C

SUMMARY OF PARAMETER RANGES / ACCURACIES

PARAMETER	RANGE	RESOLUTION OF DISPLAY	ACCURACY
Rate	5- 150bpm	.1bpm below 10; 1 bpm above 10	±10%
Tidal Vol	5- 2500ml	1ml below 200; 10 ml above 200	±10%*
Flow Rate	1- 120 lpm	.1 lpm below 10; 1 lpm above 10	±10% **
Peak Pres	0- 120cmH_2O	1 cmH_2O	±3% FS
PEEP Pres	0- 35 cmH_2O	1 cmH_2O (above baseline)	±3cm H_2O
Sensitivity	-10 to -0.2cm	.1 cmH_2O below 3; 1cm above 3	±1cm H_2O
Press Supp.	0- 50cmH_2O	1 cmH_2O (above baseline)	±3cm H_2O
SIMV Rate	.6- 30 bpm	Same as Rate	±10%
Plateau	10- 33% I	1%	±20%
Shift Delay	10- 30sec	1sec.	±2 sec
O_2 sensor	0- 100%	1%	±3% FS
Temp sensor	15-45 Deg C	.1 Deg C	±1Deg C
Exh. Tidal Vol.	100-3000 ml	1 ml	±15% ***

*Accurate from 100-2500 ml
** Accurate from 1-120 lpm ±10% of setting or 1 lpm, whichever is greater. (For units with entrainment, see Addendum 2 at the beginning of this manual).
***See ADDENDUM 1 at the beginning of this manual; readings below 100 ml may be considered relative rather than absolute.

APPENDIX D

SUMMARY OF DISABLED FUNCTIONS

DISABLING FUNCTION	MENU DISABLED IN	PARAMETER DISABLED
BABY MODE	MAIN	SENSITIVITY
		SIMV RATE
		PRESSURE SUPPORT
	SECOND	AUTO SHIFT
		PLATEAU
		NEBULIZER (DURING CPAP & SPONTANEOUS BREATHS)
	VIEW	PLATEAU PRESSURE
		SPONTANEOUS EXHMV
BABY/CPAP MODE	ALL	RATE
		INSP
		I:E RATIO
		AUTO SET
	MAIN	SENSITIVITY
		SIMV RATE
		PRESSURE SUPPORT
	SECOND	SIGH
		AUTO SHIFT
		PLATEAU
		NEBULIZER
	ALARM 1	EXHTV
		EXHMV
	ALARM 2	MEAN
		PWI
	VIEW	CORRECTED VOLUME
		TIDAL VOLUME
		EXPIRATORY TIME
CPAP	SECOND	SIGH
SIGH	SECOND	PLATEAU FOR SIGH BREATH
PLATEAU (OFF)	LUNG MECHANICS	PLATEAU PRESSURE
		STATIC COMPLIANCE
		AIRWAY RESISTANCE
EXHALED TV (OFF)	VIEW	EXHALED MINUTE VOLUME
		SPONTANEOUS MINUTE VOLUME
FLOW < 20 LPM	SECOND	NEBULIZER
RATE > 60 BPM	MAIN	SENSITIVITY

APPENDIX E

FAIL-TO-CYCLE ALARMS

SINGLE LONG TONE……	POWER FAILURE
ONE LONG, ONE SHORT TONE……	SOLENOID A
ONE LONG, TWO SHORT TONES…….	SOLENOID B
ONE LONG, THREE SHORT TONES……..	MICROPROCESSOR

APPENDIX F

EUROPEAN AGENT

Bio-Med Devices' Official Agent in Europe is:

HORST HÖRNLA

H + H Intermed
Schwedenstraße 32
87463 Dietmannsried-Reicholzried
United Germany

Telefon: 08374-240620
Fax: 08374-2406262

INDEX

A

Abbreviations, 102
AC Power, 16
Accessories, 36
Accuracies, 104
Addendums, 2
Adult Mode, 22, 26, 27
Alarm, 30
Alarm 1, 26
Alarm 2, 26
Alarm Quiet, 11, 21
Alarm Reset Switch, 20
Alarms, 7, 19, 25
Apnea, 59
Arrow Keys, 20
Assist Control, 22, 56, 59
Assisted Breath (ASIST), 29
Auto Set, 6, 20, 46
Auto Shift, 24, 59

B

BABY, 22, 24, 27
Backlight, 21
Backlight Hours, 39
Backlight Replacement, 61, 71
Backup Mode, 24
Backup Rate, 20, 59
Battery, 5, 12, 16, 31, 33, 71
Battery (BATT), 29
Battery Backed Memory, 11
Battery Refresh, 33
Battery Replacement, 9, 72

C

Calibration Menu (CAL), 23, 39, 40, 61
Cautions, 5, 9
CE Mark, 33
CMV, 22, 56
Compliance Calibration, 40
Connectors, 31
Constant Flow, 22
Contrast, 22
Controlled Breath (CONTRL), 29
Corrected Volume, 27, 40
CPAP, 19, 20, 21, 23, 24, 58

D

Date (Test Menu), 39
Deactivating Alarms, 27
Default Settings, 62, 103
Disabled Functions, 105
Disassembly, 85
Display Test, 61

E

Elapsed Hours, 39
Entrainment (ENTRN), 30
Exhaled Minute Volume, 26, 27
Exhaled Tidal Volume, 26, 28
Expiratory Time, 26
External Power, 12, 29

F

Fail to Cycle, 11, 20, 21
Filter, 55, 71
Flow, 17, 19, 29
Flow Calibration, 39, 63, 80

G

Gas Supply, 9, 31, 37

I

I/E Ratio, 17, 24, 29
IMV, 22
Inspiratory, 29
Inspiratory Effort, 23
Inspiratory Time, 22, 26

K

Keys, 17, 60

L

Languages, 62
LCD, 29, 49
Leakage, 39
LED, 20, 30
Lock, 21
Lung Mechanics, 28

M

MAIN Menu, 22
Maintenance, 51
Manual (MAN), 21
Max Press. *See* Maximum Pressure
Maximum Pressure, 19
Memory. *See* Battery Backed Memory
Minimum Minute Volume (MMV), 59
Mode Selection, 17

N

Nebulizer, 24
Notes, 5, 11

O

O2 Quiet, 22
Options (OPTS), 28
Oxygen Alarm, 21
Oxygen Sensor, 9, 32
Oxygen Sensor Calibration, 40

P

Parameter Ranges, 104
Parts List, 88
Patient Circuit, 38
Peak Pressure, 26
PEEP, 19, 23, 26
Performance Check, 63
Plateau, 24, 27
Pneumatic Calibration, 74
Pneumotach, 32
Pressure Alarm, 21
Pressure Calibration, 82
Pressure Support, 23, 57
Pressure Transducer Calibration, 40, 82
Preventative Maintenance, 71
Preventative Maintenance Parts Kits, 72
PWI, 27

Q

Quick Setup, 48

R

RAM, 39, 60
Rate, 20, 26
Refresh Battery, 33
Relief Valve, 33
ROM, 39, 61
RS-232, 32

S

Schematics, 54, 91
Secondary Menu (SEC), 23
Sensitivity, 23
Sigh, 23, 29
SIMV, 20, 22, 24, 57
SIMV Rate, 23, 57
Specifications, 35, 104
Spontaneous (SPONT), 29
Spontaneous Breaths, 22
Symbols, 14

T

Temperature, 27, 35
Temperature Alarm, 21
Temperature Sensor, 32
Test, 23
Test Menu, 39, 60, 63
Theory of Operation, 52
Tidal Volume, 20, 24, 26, 27
Touchscreen, 17, 49
Troubleshooting, 42, 83

V

Valves, 39, 61
Ver (Version), 39
View, 27
View Alarms, 26

W

Warnings, 5
Warranty, 101
Waveforms, 28